Supreme Court, U.S.
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No. 05-380

In the Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL,
PETITIONER

v.

LEROY CARHART, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

JOINT APPENDIX
(VOLUME 2)

PRISCILLA J. SMITH
Center for Reproductive Rights
120 Wall Street
New York, New York 10005
(917) 637-3600

Counsel of Record
for Respondents

PAUL D. CLEMENT
Solicitor General
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

Counsel of Record
for Petitioner

PETITION FOR A WRIT OF CERTIORARI FILED: SEPT. 23, 2005
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

No. 4:03CV3385

LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., AND JILL L. VIBHAKAR, M.D., ON BEHALF OF THEMSELVES AND THE PATIENTS THEY SERVE, PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES, AND HIS EMPLOYEES, AGENTS AND SUCCESSORS IN OFFICE, DEFENDANT

Apr. 5, 2004
9:00 a.m.

Volume 5

TRANSCRIPT OF TRIAL PROCEEDINGS, BEFORE THE HONORABLE RICHARD G. KOPF, UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFF: PRISCILLA J. SMITH
JANET CREPPS
NAN E. STRAUSS
SUZANNE NOVAK
Attorneys at Law
Center for Reproductive Rights
120 Wall Street, 14th Flr.
New York, New York 10005

JERRY M. HUG
Attorney at Law
1823 Harney Street
1004
Omaha, Nebraska 68102

FOR DEFENDANT: ANTHONY J. COPPOLINO
TERRY M. HENRY
PREEYA M. NORONHA
ANDREW I. WARDEN
U.S. Department of Justice
Civil Division - Federal
Programs Branch
P.O. Box 883
Washington, D.C. 20044

* * * * *

(Recess from 12:03 to 1:35 p.m.; all parties present)

* * * * *

[Dr. Watson A. Bowes, Jr.—Direct]

[896]

THE COURT: Before we proceed, Ms. Smith, did you [897] have an opportunity to visit with the doctor over the noon hour?

MS. SMITH: Yes, I did. Thank you.

THE COURT: Will that be sufficient?

MS. SMITH: Yes, Your Honor.

THE COURT: Thank you. Go ahead, counsel.

[Dr. Watson A. Bowes, Jr.—Direct]

BY MR. HENRY:

Q. Thank you, Your Honor. Good afternoon, Dr. Bowes. Could you tell us what your profession is?

A. I'm an obstetrician-gynecologist.

Q. And can you tell us your current position?

A. My current position is Professor Emeritus of Obstetrics and Gynecology at the University of North Carolina in Chapel Hill.

Q. Are you licensed to practice medicine?

A. I am.

Q. In what states?

A. North Carolina.

Q. Are you board certified in any particular field?

A. I'm board certified in obstetrics and gynecology and in the subspecialty of maternal fetal medicine.

Q. Can you tell the Court what maternal fetal medicine is?

A. Maternal fetal medicine is the subspecialty of obstetrics and gynecology with deals largely with high risk [898] pregnancy and fetal diagnosis and fetal therapy.

Q. Doctor, could I ask you to take a look at Defendant's Exhibit 525? It should be in the binder right there in the corner.

A. Yes.

Q. And, Doctor, can you tell us what that is?

A. This is my curriculum vitae.

Q. And it has certain personal information that has been redacted; is that correct?

A. Yes, it has.

Q. Other than that redaction, is the Defendant's Exhibit 525, is it complete?

A. It is complete.

Q. And is your CV up-to-date?

A. Yes, it is.

Q. And does it accurately reflect the matters depicted therein?

A. Yes, it does.

MR. HENRY: Your Honor, defendant moves for the admission of Defendant's Exhibit 525.

MS. SMITH: No objection, Your Honor.

THE COURT: It's received.

BY MR. HENRY:

Q. Dr. Bowes, can you briefly provide us with a summary of * * *.

* * * * *

[901]

Q. And you have remained at UNC up through the current?

A. I have been at UNC until my retirement as a fulltime faculty member in 1999. I still have positions on some committees, especially the IRB, the Institutional Review Board, that reviews research projects for the medical school.

Q. And, Doctor, are you currently involved in any professional or scholarly activities in the field of medicine?

A. My primary—primary scholarly activity at this time is serving as a co-editor-in-chief of a medical journal and obstetrical journal called Obstetrical and Gynecological Review.

Q. Is that the Obstetrical and Gynecological Survey?

A. Obstetrical and Gynecological Survey. I beg your pardon. I misspoke.

Q. And can you tell us what the Survey is?

A. The Survey is a journal that's published monthly. It abstracts articles from the obstetrical and gynecological literature, and to each abstract is appended an editorial comment. In addition to that, each month are published two or three review articles about obstetrical or gynecological topics.

Q. And can you give the Court an idea of what your responsibilities are on the Survey?

[902]

A. Well, as one of the four co-editors, we review the medical literature pertinent to obstetrics and gynecology and select the articles that are to be abstracted. We then write the editorial comments that are appended to those abstracts. We also review all of the manuscripts that are sent to us for publication as review articles.

Q. And how long have you been in your current position on the Survey?

A. Since 1992.

Q. Doctor, have you yourself published any scholarly articles?

A. Yes, I have.

Q. Can you give us an idea of how many?

A. I believe my CV records approximately 140 to 145 articles that have been submitted to journals and accepted for publication, and I have authored or co-authored approximately 25 chapters of textbooks.

Q. And the articles you've written, that sort of thing, have those been published in peer review journals?

A. Yes. Not all of them in peer review journals, but the predominant number are, and those are designated on my CV.

Q. Okay. Have you served as a peer reviewer for other journals?

A. Yes, I serve as a peer reviewer currently for two journals primarily. Obstetrics and Gynecology is the name [903] of one journal; the other is The American Journal of Obstetrics and Gynecology. From time-to-time I review articles in other journals, but my primary review responsibilities are for the two journals I just mentioned.

Q. With respect to those two journals, can you describe their status in this country?

A. Well, they would be considered the two major journals in obstetrics and gynecology in the United States.

Q. And, Doctor, are you a member of any professional organizations?

A. Yes. I'm a member of the— I'm a Fellow or a member of the American College of Obstetricians and Gynecologists, and I'm a member of the Society for Maternal Fetal Medicine.

Q. With respect to your being a Fellow at ACOG, have you served in any special capacities with that organization?

A. I served for a number of years, for five years in total, as a member of the committee on ethics, and for three years I was the chairman of that committee.

Q. What does that committee do?

A. That committee is, its primary responsibility is to write opinion papers about matters that deal with various topics of ethics in the field of obstetrics and gynecology.

Q. Doctor, are you familiar with the medical techniques used to perform abortions or terminations of pregnancy?

A. Yes.

[904]

Q. May I ask how you're familiar with those procedures?

A. I'm familiar with those procedures by virtue of my residency training and my subsequent practice of obstetrics and gynecology. Those procedures involve such things as terminating what are called incomplete miscarriages, and this would be a procedure called a D & C or a dilatation of the cervix and curettage of the uterus. That is the same procedure that has been used for terminating pregnancies, induced abortions. I'm also familiar with the procedure of suction curettage which we use in both of those settings, and I have also am familiar with and have participated in procedures in the second trimester of pregnancy such as induction of labor for fetal deaths, procedures which are similar to procedures that can be used for induced abortions.

Q. You have used the term induced abortions. Do you—Does that term distinguish something you're doing from other types of—

A. Well, I use that term in distinction to distinguish between abortions which are performed on a live—when there is a live fetus, and the procedures that are performed after a fetus has died, fetal deaths in utero or earlier in pregnancy are called miscarriages.

Q. And so you have performed the latter; is that correct?

A. I have performed the latter and on some number of [905] occasions performed those on induced abortions.

Q. Have you supervised induced abortions or terminations of pregnancy?

A. I have.

Q. In what capacity did you do that?

A. I first did that in my capacity as a resident at the University of Colorado where I was supervising junior residents in the performance of induced abortions. Most of those or at least some of those were in the first trimester, and some were in the second trimester, almost all of which were—had medical indications for abortion. Later, as in my role as a faculty member at the University of Colorado—excuse me, at the University of North Carolina, I supervised a few abortions when I was the attending physician on the obstetrical service.

Q. Doctor are you familiar with the term evidence-based medicine?

A. Yes, I am.

Q. Can you tell us how you're familiar with that?

A. Well, I'm familiar with it because of my general acquaintance with the recent medical literature and because it is a term that has been applied to the way in which we are more currently evaluating new medical procedures, new techniques that are introduced into medicine.

Q. You said currently. How long has this been around?

* * * * *

[919]

A. I can't remember the exact number, but there were a lot.

Q. And are you familiar with the intact D & X or intact D & E procedures described in those materials?

A. Yes.

Q. And you're familiar with it by reviewing, by your review of those documents?

A. By my review of those documents, yes.

Q. Doctor, based on your review and your own knowledge, would you distinguish between an intact D & X, intact D & E on the one hand and a normal, for lack of a better word, D & E resulting in disarticulation?

A. Well, my understanding, these terms, the two first terms you mentioned, intact D & X and tell me—

Q. Intact D & E.

A. And intact D & E are similar procedures. They are describing the same procedure. The issue is that the fetus is delivered intact, I mean, whereas the

procedure known as D & E, dilatation and extraction, the fetus is actually removed piecemeal or disarticulated, as the term is often referred to within the uterus, and then various bits and pieces of the fetus are removed in that procedure rather than its being removed more or less intact.

Q. Have you used D & Es in your medical career?

A. Yes.

Q. Have you ever used an intact D & E in your career?

[920]

A. No.

Q. Have you ever seen any situation where you perceived the need to use an intact D & E in your career?

A. No.

Q. And have you ever seen a situation where you perceived any advantage to using an intact D & E over other methods of abortion?

A. No, I have not.

THE COURT: Counsel, I'll be very interested in knowing whether the doctor performs abortions now or in the recent past, and whether he uses any of those techniques to do that, and I understand that we can play around with the terminology, but in order for me to fully appreciate his testimony, I'll need to know in depth his background about performing these techniques as opposed to people who have, for example, have come before him.

BY MR. HENRY:

Q. Dr. Bowes, could you address that particular issue as to the techniques you have used for terminations of pregnancy?

A. Yes. I have, my experience in performing these procedures is predominantly in situations where the fetus has died, fetal death in utero, and in which the procedure is done to complete the pregnancy or terminate the pregnancy. In a very few instances, two or three, I have been supervising physician and assisting in the procedure [921] when it was done on a live fetus while I was a faculty member at the University of North Carolina, so my experience in live fetuses in which D & E have been done is limited to only two or three. My experience in doing it with fetuses that have already died, in which many of the same techniques are involved in doing that procedure, would probably amount to over my entire career a hundred to 150.

Q. Doctor, is it your understanding that certain safety advantages are claimed for the intact D & E procedure over nonintact procedures such as the dismemberment D & E?

A. Yes.

Q. How about, is it your understanding that safety advantages are claimed for the intact D & E over, say, labor induction methods of abortion?

A. Yes.

Q. And can you just give us a summary of what you believe the advantages that are asserted for the intact D & E procedure are?

A. As I understand it, advantages asserted of the intact procedure versus the D & E procedure is that it

involves fewer passes of instruments into the uterus itself, and that thereby reducing the risk of injuring the uterus in performing the abortion procedure.

Another advantage is that in removing the fetus intact, a pathologist has a better specimen to evaluate in cases [922] where there may be some question about fetal diseases or anomalies for which the abortions have been performed and to obtain more information about that. Those are two of the advantages that have been asserted.

Now, in relationship to the procedures performed by labor induction, it's my understanding that the alleged or the asserted advantage of the intact D & E procedure is equivalent to the advantages that the D & E procedure has over those. It has been shown, I think, in some fairly convincing studies that when you compare labor induction procedures to D & E procedures at equivalent gestational ages, there is a lower incidence of complications using the D & E procedure, and because the intact dilatation is a surgical procedure rather than a medical induction procedure, the assertion has been made that they are safer. I don't know of any comparison between those two groups.

Q. Dr. Bowes, are you aware of any published peer review study in the medical literature that has evaluated the safety of an intact D & E versus a disarticulation D & E?

A. No.

Q. Would that include prospective studies?

A. It includes prospective studies and retrospective studies.

Q. Are you aware of any published peer review studies comparing the safety of intact D & E with labor induction * * *.

* * * * *

[925] I can draw.

Q. Doctor, during the course of this case, were you made aware of a study that has been submitted, and I believe accepted, for publication that compares complications between intact D & E and the traditional disarticulation D & E?

A. Yes, I have.

Q. Could I ask you to turn to Plaintiff's Exhibit number 27? Dr. Bowes, does that appear to be the study that you just mentioned?

A. Yes, it is.

Q. And can you—Have you reviewed that study?

A. I have.

Q. Could you briefly summarize for the Court what it states?

A. This study is entitled Dilation and Evacuation at Greater Than or Equal to 20 weeks: Comparison of Operative Techniques. The authors were Dr. Steven T. Chasen and several co-authors, and it's from the Department of Obstetrics and Gynecology at the Weill Medical College of Cornell University. This study was a retrospective cohort study in which included a total of about 383, if I remember the total number correctly, patients, 120 of which had the so-called intact dilatation and—I'm sorry, the dilatation and intact evac—intact D & E procedure. The other, the [926] remainder, 263 patients, had the traditional D & E procedure, and

they, in their study, compared the outcomes of these two groups of patients with regard to surgical complications, amount of bleeding, cervical lacerations and so forth, infections and so forth. That was one part of their study.

The second was they followed up the—a certain number of patients thereafter who had pregnancies after the abortion procedures and evaluated the outcomes of those pregnancies, particularly related to premature birth in the two groups. Their conclusion was that they found no difference in the complication rate between the two procedures which was about 5% in each group, and they found no difference, statistically significant difference in the incidents of premature birth in those women who they followed up at their hospital who had subsequent deliveries.

Q. Are you aware of any, or do you have an opinion concerning any limitations regarding the study and the reliability of its results?

A. Yes, I do. I have—In looking at this study, I felt there were several limitations to it. The first was, and I think the most important, is that the number of patients they have in their study is too small to allow them to state that there is no difference in outcomes in a statistically valid degree—to a statistically valid degree.

[927]

Now, this takes a little bit of explanation. When you're comparing two groups with a relatively low incidence of complications, in order to show that there is no difference and that that difference, that nondifference is significant, you need a substantially greater number of patients than they had in their study, so when they say there was no difference, there, in fact,

there was none in their data, but that does not mean there is not a difference in complication rates between these two procedures, and you just can't prove that statistically with the number of patients they had. Another critique I have of this study is that the authors did not state clearly what their follow up procedure was; in other words, how many patients in this study did they actually see after they had their abortions, how long did they follow them and so forth. In other words, did they lose, were there adverse events that they didn't know about; in other words, the patient may have had a complication and went to some other hospital. They simply do not document how they followed the patients up. Third, the groups in these two, the patients in these two groups were quite different. They were different in age, they were different in the gestational duration of pregnancy at which the procedures were done, they were different in the indications for which the abortions were performed, so that means that the populations were quite heterogenous, and it's [928] difficult to compare them in that situation to know if these differences might have been confounding factors in the study.

Q. Doctor, can I ask you with respect to that point, is there a way in studies in medical literature, or is it possible to control or to account for—

A. Yeah. One of the—one of the epidemiological methods of adjusting for those so-called confounding features is a method called regression techniques or regression analysis. I'm not a statistician, so I only know that they use these, but what this does, it takes into account all of those differences and adjusts for them. There weren't enough patients in this study to do that really, and the authors admit that. I mean, they

say that, but that is a limitation of the study; and finally, in following up the patients who eventually became pregnant, not all those patients came back to their hospital for obstetrical care, so the ones who didn't, they didn't follow up, plus there was a small number of them. They had so few patients in that study that it was very clear they could not state unequivocally with any statistical validity that there was any difference in outcoming those pregnancies, so I think that overall summarizes my critique of Dr. Chasen's and his co-author's article.

Q. Let me ask you this: You previously in your testimony [929] talked about the issue of, I believe, selections bias. Do you have any concerns in that regard from this study?

A. Well—

MS. SMITH: Objection, Your Honor. There was no opinion expressed on opinion bias in either the expert report I was given at the lunch break or in our conversation with Dr. Bowes, unless I'm not understanding where you're going with that. Okay, Your Honor. We have resolved it. I have withdrawn my objection.

THE COURT: Thank you. Go ahead.

THE WITNESS: Well, the criticism I have already mentioned in that, the populations were homogenous because of the difference in indication for the procedures that were done and so forth is a form of selection bias. I mean, it's just that the patients were not selected with equivalent indications, with equivalent ages and so forth, so there is a bias there in that, and so I think that's an important thing. One critique I did not mention, if I may.

BY MR. HENRY:

Q. Go ahead.

A. Is that the way in which they decided which patient would have which procedure is not dealt with in any great detail; in other words, although only two of the authors were involved in performing the abortions. According to the article, they did not say what were the precise criteria. [930] They said in general it had to do with how far the cervix was dilated and the position of the fetus, but they made that decision at the time they were about to perform the procedure, but they didn't go into any great detail about the very specific objective criteria suggesting there may not have been any one. It may have been just their intuition. We go back to intuition, or their hunch that one procedure would be better than the other, and I think that's a limitation.

Q. Doctor, are you familiar with the author or one of the authors of this study, Dr. Chasen?

A. Only in my awareness that he's written this article. I do not know Dr. Chasen personally or professionally.

Q. Do you know whether or not he's involved in any of the cases challenging the Partial-Birth Abortion Ban Act of 2003?

A. Well, he is because I read his—I think he has one of those statements that I was—

Q. Like an expert report?

A. An expert report.

Q. And does—Do you have an opinion as to whether Dr. Chasen's role in this litigation in any way impacts the study or value of the study or that sort of thing?

A. Well, I can't—I could not state that. I don't want to impune Dr. Chasen for any ulterior motives here, but I [931] think it would be appropriate for the author in this circumstance to at least have disclosed to the journal to which he's submitting this that he was involved in this case. I say that because, for example, if an author of a study is in the employment of a drug company and they are studying a drug, a drug that company manufactures, it's mandatory that the journal knows and that it's disclosed in the article when it's published so the readers know. Now, they can draw any conclusions they want to about that. I'm not going to draw any conclusion about Dr. Chasen though.

Q. Doctor, do you have an opinion regarding whether this study proves or does not prove the comparative superiority and efficacy or safety of intact D & E versus D & E by disarticulation?

A. I have an opinion, yes.

Q. Can you tell the Court what that is?

A. Yeah, I believe this study does not prove the superiority of one of these procedures over the other. I think for the reasons I have mentioned, the lack of sufficient numbers and of the other criticisms. I have said that I don't think it proves that one procedure is better than the other.

Q. Doctor, a general question. Just because an article is being published in a peer-reviewed journal, does that mean it's without flaws?

[932]

A. No. It does not mean it's without flaws. The peer review process is just one level of scrutiny. Often an article that gets into the peer review journal after being—in a journal after being peer reviewed will be pilloried by letters to the editor pointing out all kinds of things the peer reviewers either overlooked or the editors overlooked, so I don't mean it's—Peer review is certainly not without its value, but it doesn't mean that every article is absolutely spotless after it has been accepted for a peer review journal.

Q. Doctor, I believe you testified before, you're aware of claims or arguments that—of potential safety advantages for intact D & E versus other methods of abortion. Do you have an opinion as to the validity of those claims from an evidence-based medicine standpoint?

A. Well, I don't think those claims can be supported by evidence-based medicine. If I may expand on that, I know that Dr. Chasen and his colleagues suggested that because the group of patients who had the intact D & E procedures, the intact procedure were about two weeks further along in their gestations than the group that had D & Es, and that they found no difference between the populations in terms of complications, and because there is a general impression that the further you get in pregnancy, the more complicated an abortion procedure becomes, then, therefore, because [933] there was no difference, this procedure must be safer because they had more patients who were done later. My response to that is, A, to begin with, they don't have statistical validity to their claim that there was no difference in these procedures; and secondly, it's pure conjecture to

make those leaps between those, those foundation arguments that I just mentioned.

You would have to prove that with good statistical analysis in a comparative study that was designed to do that.

Q. Doctor, could a study sufficient to draw some reliable conclusions be done comparing intact D & E with D & E? Do you have an opinion about that?

A. I believe it could be done.

Q. How about a study comparing intact D & E with labor induction abortion methods?

A. I believe that could be done, too.

Q. What types of studies could be done with regard to those issues?

A. Well, although it would not be easy, I didn't claim it would be easy, I believe you could conduct a study under proper circumstances and with proper design of the study that would be prospective. You could assign patients randomly to one procedure or the other at various gestational ages and look at the outcome. Also, you could * * *.

* * * * *

[Dr. Watson A. Bowes, Jr.—Cross]

[970]

A. Well, you could never perform it in that setting or in that type. You might be able, as Dr. Grimes suggests, to do it in another setting.

Q. In a different country?

A. In a different country, or you modify the procedure so it didn't, it didn't fall into the ban.

Q. But then you wouldn't be able to study the procedure before it was modified; would you?

A. No, you would be studying a modified procedure, but it would relate to the surgical technique that's being studied.

Q. And you would agree, Doctor, don't you, that as long as there isn't a high rate of complications from a new technique or a variation of a technique, that until there's a sufficient number of times in which the technique has been performed, such that it can be properly studied retrospectively, it's appropriate to leave the use of the technique to the informed judgment of responsible physicians; don't you? That was a very long question.

A. Yeah. I guess what you're asking, I don't want to put words in your mouth either, but are you asking me that until you have enough patients to do the study, you can't accomplish it, so you assume that it's going to be performed in the community by some physicians? Yes.

Q. And I added a little bit to that which is that if there is not a high rate of complications coming along with the [971] procedure, that you would continue with the procedure until you could study it?

A. Yes.

Q. And, Dr. Bowes, you haven't figured out how many intact D & Es that would need to be performed before you could do a retrospective case-controlled study; have you?

A. No.

Q. And you would agree that if a retrospective study were published in a peer-reviewed journal such

as the American Journal of Obstetrics and Gynecology, the peer review process would provide some assurance that the study had been responsibly and reliably conducted; wouldn't you?

A. Some assurance.

Q. Before we talk about Dr. Chasen's study, which I know we are dying to do, I wanted to ask you a few questions about fetal demise and inducing fetal demise prior to a procedure. In the handful of second trimester abortions that you've participated in since your residency, you didn't inject potassium chloride into the fetal heart or Digoxin into the amniotic sack or into the fetus to cause fetal demise before you began the procedure; did you?

A. Not those specific drugs, but the drugs we were using for induced abortions by the labor techniques involved either saline or urea which in their own right cause fetal demise.

[972]

Q. But in the D & Es that you were involved in, Doctor, you didn't ensure fetal demise prior to the extraction?

A. I'm sorry, as you said D & E. No, we did not.

Q. I didn't clarify it, so you were correct. I thank you, Doctor. And you didn't do that because you don't believe there is any medical benefit to the woman of injecting such substances to cause fetal demise in the second trimester; isn't that right?

A. There is no benefit to the woman.

Q. And there is no medical benefit—Sorry. There is no medical reason to subject a woman to an extra procedure that affords her no benefit; isn't that right?

A. That's correct.

Q. And you agree that such injections cannot practicably be given to all women in all circumstances; don't you?

A. That's correct.

Q. For example, it would be difficult to use those injections in a morbidly obese woman; isn't that right?

A. Yes, ma'am.

Q. And with respect to injections of KCL into the heart, you would agree, Dr. Bowes, would you not, that not all physicians have the skill to perform such injections?

A. I would agree with that.

Q. And, in fact, defense counsel asked you if you would state in your expert report that it's easy to administer * * *.

* * * * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

No. 4:03CV3385

LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., AND JILL L. VIBHAKAR, M.D., ON BEHALF OF THEMSELVES AND THE PATIENTS THEY SERVE, PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES, AND HIS EMPLOYEES, AGENTS AND SUCCESSORS IN OFFICE, DEFENDANT

Apr. 6, 2004
9:00 a.m.

Volume 6

TRANSCRIPT OF TRIAL PROCEEDINGS, BEFORE THE HONORABLE RICHARD G. KOPF, UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFFS: PRISCILLA J. SMITH
JANET CREPPS
NAN E. STRAUSS
Attorneys at Law
Center for Reproductive Rights
120 Wall Street, 14th Flr.
New York, New York 10005

JERRY M. HUG
Attorney at Law
1823 Harney Street
Suite 1004
Omaha, Nebraska 68102

FOR DEFENDANT: ANTHONY J. COPPOLINO
TERRY M. HENRY
PREEYA M. NORONHA
ANDREW I. WARDEN
U.S. Department of Justice
Civil Division – Federal
Programs Branch
P.O. Box 883
Washington, D.C. 20044

* * * * *

[Dr. M. LeRoy Sprang—Direct]

[1098] take our lunch break now?

MS. NORONHA: Yes, Your Honor.

THE COURT: Is in agreeable? All right. Since we went a little bit late, why don't you come back at say 1:45 please. We'll stand in recess. I do have a criminal matter in here over the noon hour so you may want to push your stuff forward.

(Recess at 12:18 p.m. 1:45 p.m.; all parties present).

THE COURT: Mr. Henry?

MR. HENRY: Your Honor, defendant calls Dr. LeRoy Sprang.

Dr. M. Leroy Sprang, defendant's witness, sworn.

THE COURT: You may inquire.

BY MR. HENRY:

Q. Thank you. Good afternoon, Dr. Sprang. Could you tell us your profession, please?

A. I'm a practicing obstetrician-gynecologist.

Q. And are you board certified in obstetrics and gynecology?

A. I'm board certified in obstetrics and gynecology.

Q. Are you licensed to practice medicine?

A. I'm licensed to practice medicine in the State of Illinois.

Q. Doctor, if you would, please, take a look at Defendant's [1099] Exhibit 530. Is that a copy of your CV with certain home residence information redacted?

A. It does appear to be, yes.

Q. And is your CV up-to-date?

A. It does appear to be.

Q. And is it—are the items depicted therein accurate?

A. Correct.

MR. HENRY: Now, Your Honor, I move the admission of Defendant's 530.

MS. CREPPS: No objection.

THE COURT: It's received. Doctor, could I trouble you to put your elbows on that bench in front of you and that will force you into the microphone.

THE WITNESS: Thank you.

THE COURT: You're welcome. Go ahead.

BY MR. HENRY:

Q. Dr. Sprang, could you describe your medical education and training for us, please, just kind of briefly give us a rundown, if you would?

A. I graduated from Loyola Medical School, School of Medicine in 1969. Had a first one-year residency in obstetrics and gynecology at St. Francis Hospital. Went into the United States Navy for two years; was assigned to the United States Marine Corps, after which time I returned and finished the obstetric and gynecological residency from * * *.

* * * * *

[1101] involved in Chicago Medical Society; served as chair of many of their committees including Chairman of the Physician Review Committee. I currently am Chairman of the Ethical Relations Committee and have been for about the last ten years. I have held all the offices at Chicago Medical Society including Chairman of the Board and President of the Chicago Medical Society. I have done very similar things at the Illinois State Medical Society; served on a number of committees including being Chairman of the Board of Trustees, and president of that organization, which allows you to go around throughout the state and give presentations to many various physician groups and hospitals and see what is going on in different parts of the state in different hospitals. You can have a much broader base. And been involved in the American Medical Association and have been a Delegate to the American Medical Association from Illinois for at least the last ten or 12 years. I was an alternate delegate before that. I currently am Chairman of the Illinois Delegation to the American Medical Association, and have, because of that, have had discussions with many physicians from all over the United States on many

areas including some of the areas we are going to discuss today.

Q. Doctor, could you tell us a little bit about your private practice and what it involves, what kind of procedures and that sort of thing?

[1102]

A. I have a very large private practice. I'm in the biggest group, and probably the biggest obstetric and gynecologic group in the State of Illinois. I just put together a group of 238 obstetrician-gynecologists and am president of that group. Personally, I have delivered over 3,000 babies into the world over the last 25 or 30 years. I do the full range of obstetrics and gynecology, normal risk and high risk obstetrics. In the beginning, before the subspecialty of high risk obstetrics existed, our group provided the high risk obstetric care. We still have a relationship with maternal fetal medicine patients that when we have a high risk patient, we get consult from them, but they do send them back to us for continued care. I do all surgical procedures in any typical fashion of gynecology.

Q. Doctor, are you a fellow of ACOG?

A. I'm a fellow of the American College of Obstetricians Gynecologists, and a fellow of the American College of Surgeons. Individual I trained with was very surgically oriented and felt we should actually be able to be fellows in both those organizations.

Q. Doctor, have you published any books or articles in the medical field?

A. I have published a reasonable number of articles probably totaled about 20, some in more peer reviewed, some in some of the organizational types of journals as

well. I [1103] have written a book chapter, I have been a reviewer for the American Journal of Obstetrics and Gynecology which all the articles have been presented have come from. I have edited other pamphlets and have been Chief Editor for Chicago Medicine and a number of things like that.

Q. Okay. And are your articles, the stuff you mentioned, is that indicated on your CV?

A. It is on my CV, and the chapter of the textbook is on obstetric and gynecologic infections.

Q. Do you consider that a special interest in your practice?

A. I have had a special interest in obstetric and gynecologic infections, practically pretty much from the beginning of going into practice, and have lectured probably hundreds of times in national and local programs. I have lectured at the American College of Obstetricians and Gynecologist annual meeting; American College of Surgeons, family practice, internal medicine, and a number of major national and have been a speaker AMA leadership conferences on several occasions.

Q. Doctor, are you also involved in the risk management work?

A. I do a fair amount of that as well. One of the other boards I sit on, which I have chaired, is the Illinois State Medical Society Insurance Company, liability insurance [1104] carrier. It's the biggest liability carrier in the State of Illinois. We have 14,000 policy holders. I chair various committees there, and have chaired the board. We review all of the cases that come forward each month. We have different review committees that go through each of the cases. So I see a lot

of the types of errands that are—errands, some of them are legitimate but some of them are not. It gives you a chance to see what's going on in gynecological surgery obstetrics and where we do or don't see lawsuits being filed. So we have a feel for the applications that occur in practice as well.

Q. Doctor, I would like to ask you some questions regarding your familiarity, if any, with methods of abortion. Let me ask you, in your practice, have you, yourself, had to remove products of conception before pregnancy reaches term?

A. I have, and they are obviously kind of medical and CDC definitions of abortion. Commonly people, when they are using a CDC definition, would mean the fetus is alive before the physician intervenes, in some fashion, and terminates the pregnancy. Medical terminology would include abortions have a much broader term for that. We would use even like spontaneous abortions, which the vernacular would be like a miscarriage. So I have actually, again, if I have delivered over 3,000 babies, approximately 15% of pregnancies end in a miscarriage and abortion. So I have managed at least 450, [1105] 500 patients with those types of abortions. And we have also done it at each of the different stages at the first trimester, the second trimester and the third trimester.

Q. Aside from miscarriages, have you dealt with situations involving removing a fetus when it had died while in utero?

A. Yes, and at each first, second, third trimesters, yes.

Q. Can you tell us the different methods of removing fetuses?

THE COURT: Counsel, it would be helpful if—and I'll leave it to your good judgment—but helpful for me to know if the doctor has performed and if so, when, abortions as defined by the CDC.

BY MR. HENRY:

Q. Doctor, have you performed abortions as defined by the CDC, which, I believe, Your Honor, is referring to abortions on live fetuses; is that correct?

THE COURT: The doctor gave his understanding of it and that's mine as well.

THE WITNESS: Right. The definition would be where you're starting the procedure with a live fetus and ending up with a dead fetus. And I would be in circumstances where that has occurred, yes. Has that been initial goal? Not really. And, actually, I think in my deposition, I couldn't think of a time when I have done that. There—were * * *.

* * * * *

[1140] are asking a witness questions from these big books, they ought to be required to hold the big books themselves. And then that will remind them that handling these things is a little bit like lifting weights.

THE WITNESS: That's a very good idea.

THE COURT: Go ahead.

BY MR. HENRY:

Q. Doctor, are you familiar with a method of abortion that has been referred to as intact D & Xs?

A. Yes, I am.

Q. Is it sometimes referred to or is it similar to a procedure known as intact D & E, to your knowledge?

A. Yes. There are several different people who use different means, and whether it's McMahon or Haskell, or I will call it intact D & X, because that's what the American College of Obstetricians and Gynecologists wish to call it. And that's what the American Medical Association has said is the appropriate term, and they have defined it.

Q. And how did you become familiar with this particular technique?

A. For the reasons we said before, sitting on the AMA committee. And I'm also strongly involved in American College of Obstetricians and Gynecologists, and talk to the President of ACOG, at the time that they formed that definition.

[1141]

Q. And when you're talking about that definition with respect to ACOG, are you talking about the statement on intact dilation and extraction?

A. Correct.

Q. Dated approximately 1997; is that correct?

A. I can look it up. '96, '97, yes.

Q. Did you take a look at Defendant's Exhibit 651? Is that the ACOG statement you're referring to?

A. It appears to be.

Q. Could you also take a look at Defendant's Exhibit 580?

A. 580.

Q. I believe earlier you had mentioned Dr. Haskell. Defendant's 580 is a paper entitled Dilation and Extrac-

tion for Late Second Trimester Abortions by Dr. Haskell. Have you read that paper before?

A. I definitely saw his presentation National Abortion Federation, and I'm not 100% sure this is the same one. I would have to look at it a little bit.

Q. Is there any other way you made yourself familiar with the procedure known as intact D & X?

A. Again, speaking with different physicians who do it, and again, speaking with physicians at the AMA. Again, in that room, there were probably a thousand physicians from all over the United States in all specialties. And the American College of OB/GYN had their delegation there too. So [1142] I frequently speak with them.

Q. Based on what you have learned, could you describe to us the X of the intact D & X procedure as you understand it?

A. Again, there are multiple definitions, so I'll use ACOG's, because it's an organization that I belong to, along with some of the others. Their definition is a gradual dilation of a cervix, usually over days, usually over two or three days. Once there is completed dilatation, there is instrumental inversion, what we a podalic, an internal podalic inversion of the fetus from a vertex presentation to a breech presentation. You reach in—usually they reach in with an instrument, try to grab a foot. They rarely can get both, and forcefully turn the fetus in the uterine cavity to make it do a somersault so the feet present. The third is then basically doing a total breech extraction. As a resident, I probably did 50 of those and probably done 100 in my career, and that's what they are doing. They are doing a total breech extraction on a fetus, typically between

20 and 26 weeks. That's the most common time Haskell says he uses it, and it's a twisting, turning motion with a certain amount of traction. And depending on cervical dilatation and potential trauma to the cervix, pulling it through the cervix. And depending on how much dilatation and size of the fetus, sometimes it will come * * *.

* * * * *

[1145] one of the—and I won't mention names.

Q. Doctor, let me ask you, what does friability mean?

A. How easy does something break apart. If you are trying to extract a fetus at 14, 15 weeks, it's much softer much more cartilage, soft tissue. If you grasp it, you're probably just going to pull off whatever you grasp. As you pull on it it's not going to stay intact. It's not going to come down in one piece, because it is too soft to do that. It's cartilage, not bone. It's just more friable tissue.

Q. Doctor, are there features that you consider specifically distinguish the intact D & E and D & X procedure from, say a traditional disarticulation D & E?

A. No. There are several, I mean, and there may be nuances, there may be—I'll give the several things that are appearing to me. They may not all be 100%. As you go through the definitions. In general, you are putting laminaria in, which do carry some risks. By putting them in multiple times carry some risk. But you're trying to get a greater dilatation of the cervix. To do the D & E, you need less dilatation, because you're crushing the parts or the parts. You're bringing through the cervical os are smaller. For intact D & X, you need, at least according to Haskell, at least five or

centimeters of dilation. To do that, you're usually putting laminaria in and putting more laminaria in.

The first day, Haskell says he puts in [1146] half-a-dozen, so the process is a three-day process. The first day, he puts in about, first mechanically dilates the cervix. Puts in about a half-a-dozen laminaria. The patient goes back to—if she's from out of town, back to a motel. Is having cramping and discomfort, and hopefully, she has a friend or somebody with her. The laminaria are expanding, dilating and dilating the cervix over that 24-hour period. The next day, he sees her in the office again, removes those laminaria, and puts in, by his definition, 20 to 25 laminaria. That's a lot of laminaria. And you're forcing them in to get maximum expansion of the cervix. Patient goes wherever she goes again for another 24 hours, and then comes back to his clinic again. And on the third day, he pulls out the laminaria and sees how much dilation he has. And, hopefully, he has enough that he feels he can do the procedure. At that point, then she goes into the operating room and anesthesia and prep, and then he breaks the bag and uses suctions, gets out the fluid, and then does then what we described as the intact D & X. How much detail do you want?

Q. That's fine. So you mention the kind of multi-day aspect of the process?

A. Yeah, and the amount of cervical dilatation.

Q. Right. Anything else?

A. The actual procedure. You're doing an internal podalic [1147] version, which, as I have said in my paper, Williams Textbook of Obstetrics says there is seldom, if any, indication for doing this procedure, other than maybe for the second twin. He does go on to say

that there is risk of rupturing the uterus by doing that procedure and he actually says it's the most common cause of traumatic rupture of the uterus. It is true, the whole process is smaller here, but if you are still doing it at 25 weeks, you do it in twins at 30 weeks, that's getting pretty close to the same thing.

Q. Doctor, you mentioned Williams Obstetrics. Do you know the current version of Williams Obstetrics as the assertion that you talked about?

A. What they have done, because that procedure is done less and less in obstetrics, again, being an editor an reviewer for textbooks as well. As new information comes out, now external versions are much more common than internal versions, and you only have so much space in the book. And you only have so many pages. So they have expanded the section on external version, which is now much more common obstetrics, and you have a much smaller paragraph on internal versions.

Q. Okay. Doctor, if I could, I wanted to ask you, based on your training, experience as an OB/GYN, your knowledge of medical literature, do you have an opinion as to whether the [1148] intact D & X procedure presents significant risk to the woman?

A. I believe it does.

Q. Could you just briefly list kind of what those risks are?

A. My concerns with the procedure are several things that distinguish it from the traditional D & E. The fact that it—more commonly for D & E, you can dilate the cervix over one day. There may be exceptions. But in general, more commonly one day. More commonly for a D & X, you're dilating it over two days.

Q. Does that present a risk?

A. Presents several problems. Laminaria are these little seaweed sticks that you're placing in the uterus, and they have to cover the entire length of the cervix. They have to be from the outside to the inside to make sure the entire cervix dilates evenly. Again, infectious disease is my area of expertise. You put a foreign body that's sitting in the vagina and inside the uterus, that vagina normally has five to nine different types of bacteria in huge, huge quantities, ten to the nine. Bacteria have a better chance moving along the laminaria and getting inside the endocervical os and running a risk of infection, because they are in contact with the vagina, and up against the amniotic sack. That's the issue. There is a certain amount [1149] of trauma in just the fact there's a foreign body. There is a risk. By doing that two days, it's just there longer. There is more risk. In the descriptions I have read on occasion, including Haskell, he says sometimes when you go back the second day, the bag breaks. But he still puts his laminaria in, and still waits for the next day. Well, once the bag breaks and you have a foreign body sitting there and the bacteria are getting from the vagina to the uterus, that's a recipe for disaster. They use prophylactic antibiotics during all this, so they are trying to do something to protect against that too. Again, it's different from D & X because the duration is longer.

Q. You're talking about the risk of infection?

A. Correct, and trauma to the cervix. If you are dilating the cervix to a greater degree, some of it is mechanical. You mechanically dilate first before he puts the first laminaria in. I have been told by some —the people, some or at least one of the people who

does that, that they force as many laminaria in as possible on the second day because they want the greatest amount of dilatation as possible because that will make the delivery process easier. So it's not just slow dilation from laminaria taking in fluid, there is some mechanical aspects to it too. And that, I think, does more risk to the cervix. And, clearly, at least theoretically, that risk—

[1150]

Q. What kind of rise to the cervix are you talking to?

A. You traumatize the cervix. And there is information on earlier ones, which even dilate mechanically now, dilate the cervix either from 10 millimeters to 11 millimeters, it increases the risk of an incompetent cervix later. The cervix not being able to maintain a pregnancy or maybe just weak enough you have more preterm deliveries. And preterm deliveries are the single greatest medical obstetrical problem in the United States today.

Q. So are you saying preterm deliveries are caused by the incompetent cervix?

A. By weakness of the cervix.

Q. Okay. Are there any other aspects of the D & X procedure that contribute to—

A. The next thing that is unique, is that you are doing the internal podalic version, and we talked about that. Yes, it is smaller, but so is the uterus smaller. So, relatively, the uterus, and the placenta, and the fetus are more comparable. And, again, you're doing them later, so the uterus is already starting to soften more, and there is greater risk of trauma in uterine rupture.

By mechanically doing that, this is not easy. We are physically, forcefully pulling this. And I don't think people have any idea—when we gently deliver a baby with low forceps, sometimes your feet are on the thing, you're going like this. The [1151] things we do are mechanically forceful.

Q. So have you done one of these podalic versions?

A. I have done numerous podalic versions.

Q. At term?

A. At second twin, where you're all-of-a-sudden heart tones look bad, one twin is out, one twin is in. You have either got to get that twin out of there or do a crash cesarean section. In that environment and doing the internal podalic version, I trained at a time when those were more common and more acceptable, and today, probably more people would just do a C section. They wouldn't even do it. But in doing that, the risk of ruptures there, first off, these are rare things. Pulmonary embolus—we do 500 or a thousand before you see one. But it's there. When you separate and you are doing that much force, if the placenta separates, the maternal blood vascular supply is then exposed. And some amniotic fluid or some of the vernix from the baby are particles and go along, and you have a pulmonary embolism and amniotic fluid embolism, which is serious, potentially half of them dies. Potentially life threatening. Assuming that doesn't happen, you finish, you do the breech extraction, which is, again, doing what we used to do just to deliver the babies vaginally, when they are breech, but again, stopping at the neck, not all the time, some of the time, and concerns me, if it doesn't stop at the neck. What * * *.

* * * * *

[1154]

delivering the fetus. Then what do you do?

Q. Does it affect any risk, with respect to the D & X procedure, in your opinion?

A. If—it may. It serves some advantage, if you really actually can use it effectively to dilate the cervix, and the cervix is more and more out of the way, there is probably going to be less trauma to the cervix.

Q. Doctor, do you believe there is any risk associated with this procedure when—with regard to the aspect of this procedure, when it's used of piercing the skull and suctioning the cranium contents?

A. My theory in that, as I pointed out, the way Dr. Haskell describes it you're trying to pull down on the head all with the same hand, and with the other two fingers of the same hand, push the cervix up out of the way, so you can see the lower portion of the head, if it's trapped there. And then trying to slide in the scissors and pierce the skull. In most of the other D & Es, they are not using, at least I know they cut off portions of the baby sometimes, the fetus or partially delivered child, whatever word you want to use. But this is going into the skull, into the cervix somewhat blindly, depending on how far down it is. You're in the cervical area. It is quite effaced. Very vascular area. The pregnant uterus has a tremendous blood supply. The uterine arteries come in a little above that at the level of [1155] the internal os. Theoretically, using sharp instruments there poses a risk of cervical laceration. And I'm not going to say it's a tremendously high risk, but you're using sharp instruments blindly in a very vascular area.

Q. Doctor, we have talked about some of the risk. I would like to talk about some of the possible or arguable advantages of an intact D & X procedure. Would, if the intact D & X procedure, you know, where the fetus is removed intact up to some level, would it present any significant advantage, with respect to other abortion methods, with regard to leaving fetal parts or fetal pieces in the uterus?

A. Clearly, if you have everything intact, that concern would be significantly less. At the same time, with most D & Es, it's not that many parts. You can both—if you have all the parts out, put them back together and see if the fetus is all there. You can feel with your fingers, and I'm going to say is the golden standard, I believe you should have an ultrasound sitting right next to you all the time. And I think that any question, you should be using the ultrasound as well. There is numerous articles on just using ultrasound, even just to do the procedure dramatically takes it safer both in grasping and in telling you whether there is anything still there.

Q. That was my question. So you are using the ultrasound to determine if there is any fetal part left?

[1156]

A. And you use your fingers, and you can take the parts out; you have them, and look at them, and you're still going to go back in and suction and make sure you have the placenta, and you have all the tissue.

Q. And you mentioned the grasping aspect of it. Are you saying ultrasound affects any risks that would be posed by that?

A. Significantly decreases the risk, and there is a study again in the Clinical Guide to Surgical and Ob-

stetrical Abortions, and that using ultrasound decreased the risk from like 1.4% to .2%. There is actually a beautiful picture in there that I like, because the metal instruments reflect the ultrasound very, very well, they can see these two beautiful clear, white grasping things. You can see the skull there. You can see it. Picked it up nicely and more carefully slide out. It gives you better control. It's like you want to do something with the lights turned on in the room or whether you want to do something with the lights turned off in the room.

Q. So you're saying the use of ultrasound would reduce the potential for—

A. Both trauma and leaving any fetal parts in there.

Q. And trauma, that would be from any instruments you're using?

A. The risk and, again, it's the experience of the [1157] physician makes a huge difference. I have done 500 D & Cs or something, and I have never perforated the uterus, and that's in pregnancy and not pregnancy. It's just finesse and skill and your ability to do it. If somebody doesn't have any finesse, then they are much more likely going to go through the uterus, because they don't know where they are.

Q. Doctor, are you aware of any published studies comparing the safety and risk of intact D & X with dismemberment D & E? I'm talking about published things.

A. I'm not aware of any published studies.

Q. During the course of this case, were you made aware of a study that had been submitted for publi-

cation that compares complications or safety of intact D & X versus disarticulation D & E?

A. I did see that study.

Q. Could you turn to Plaintiff's Exhibit 27? Okay. Doctor, have you reviewed the study that's reproduced at Plaintiff's 27?

A. I have.

Q. Can you briefly tell us what the study is, and just give us a quick summary?

A. Basically, it's a study of 383 patients comparing D & E, traditional D & E, and their definition of D & X. I have not seen a definition like this, because it certainly doesn't follow ACOG's, or Haskell, or McMahon's definitions [1158] of the intact D & X. Seems to me, they kind of made up their own.

Q. Do you know how many studies were involved in each group?

A. Out of the 383 patients, they had what they called intact dilatation extraction in 120 cases, and 263 cases of D & E.

Q. Can you tell us what the results of the study were?

A. What they said is they looked at the complications. They said the overt complication rates were essentially the same. There were no second trimester miscarriages. They did say, and seems very relevant to me, even though they said it wasn't. They said there were two of of 17 or 11.8% of those, 12% of the patients who had a D & X at preterm labor. Only 4.4 %, almost a three-to-one ratio of patients with D & E had a preterm

labor. Because the numbers are so slow and one of the weaknesses—

Q. Well, let's talk about some of the weaknesses. Could you just kind of catalog what you think any of the weaknesses are?

A. Because some of the large weakness, still the numbers were so small and the number of complications were small enough that they didn't have any power. They didn't have any meaning where you could say they were statistically significant, because there is so few cases that something [1159] would have to happen, one; and two, for it to even show anything. When things don't happen as often, you need many more patients to look at for the statisticians to tell you, this have a chance or enough power to actually distinguish a change—a difference between the two. But even though the power was very minimal, there is no significance, statistical significance; a difference between 12% and 4% certainly would indicate a trend. And, certainly, if anything from the trend from that would clearly say D & Es are the better of the two. They have less preterm labor.

Q. Can you tell for sure anything from a trend, when you have statistically insignificant numbers?

A. You look at it and say maybe this deserves further studies. You certainly can't say they are dissimilar and just blow it off, when it's one is three-to-one. They also said that the complication rates were kind of similar and when you look at the complication rate for lacerations, which is what we are talking about, our concern about doing an intact D & X is that it's just bigger. If you bring something bigger through the cervix, the vagina, the peritoneum, you're going to do

more trauma. I looked at these numbers myself, and I have to kind of come off the top of my head. The lacerations for D & X were like 3 1/2 %. The lacerations for D & E were 1 1/2% to, again, it was like two-to-one.

[1160]

Q. Is that another trend?

A. It's clearly a trend. Numbers are so small that I can't say that's a statistically significant difference, but that's a fault of the study. The study has so few cases that you can't say anything is statistically significant. They conclude that the two are comparable. There is certainly nothing there that says D & X is superior in any way, and I would say the trends for both of those, which are major issues that I talked about in my paper, trauma to the cervix, preterm labor, those kinds of things defend—would support that D & X has more risk than D & E.

Q Are there any other concerns that you have with the study, methodology and your conclusions?

A. They have very small follow-up. They started out with that number of patients, but then for deliveries afterward, they looked at—they only looked at those patients that subsequently delivered in their institution. So they excluded a great many of the patients. And you exclude them, you don't know whether that's —how meaningful that is or not. They looked at 62 subsequent pregnancies which, again, the numbers are too small to be meaningful.

Q. Does the fact—

THE COURT: Hold on just a minute, please. The court reporter needs to change his paper. Go ahead.

BY MR. HENRY:

[1161]

Q. Dr. Sprang, does the status of the study, as being in a prepublication status, as I understand it, does that concern you in any way?

A. The fact that it's not even published yet—really haven't had any ability for the medical community to respond and make any comments. Sometimes, especially on controversial issues and issues like this, they will be discussed at journal clubs or at different hospital departments. Sometimes at various meetings, sometimes you'll even get letters to the editor kind of saying, why did you publish a study with such low numbers that nothing statistically significant or pointing out the trends were actually greater, and they had clearly more studies needed to be done. And when they came to conclusions that they did, it just didn't seem to me that their data is substantiated by the numbers they have. They concluded that, again, an abortion after 20 weeks with intact D & X appears to have similar rates as D & E. That—certainly, the trend doesn't say that. They observe complication rates in subsequent obstetric outcomes appear comparable. I don't senior three-to-one in favor of the D & E comparable. And then all he did was gave ACOG's policy statement, so that it was not—it wasn't consistent. It didn't meet with the data.

Q. Tell us what. I'm done with that. Doctor, have you ever performed an intact D & X procedure?

A. I have not.

[1162]

Q. In your practice, have you ever seen the need for it?

A. I have not.

Q. Your practice involves high risk obstetrics; is that correct?

A. Full range including high risk obstetrics and, again, I'm now president of a group of like 27, 28 OB providers. So I have seen a great number of circumstances. With our issues, they do clearly present them to me and I have never seen that.

Q. Would that be true even of situations involving serious maternal health conditions?

A. I have never seen a situation where a D & X would be the safest, the best, or the only procedure to use to protect the health of the mother.

Q. And that would be even in emergency situations where the pregnancy needs to be terminated and very quickly?

A. I have never seen a situation where intact D & X would be required, or the best procedure to do. In reading all the other declarations and stuff, I haven't seen a single physician who provides it do that. The AMA committee that I sat on could—and there were several different obstetricians and Counsel on Scientific Affairs. Nobody could come up with a situation where the intact D & X would be necessary to preserve the health of the mother. In ACOG, [1163] when they had their panel, could not come up with—they couldn't come up with a single example where it would be, you know, the best, most appropriate alternative to save the health of the mother or to have a beneficial effect on the health of the mother.

Q. Doctor, have you ever performed a hysterotomies?

A. We perform them all the time. That's what a cesarean section is.

Q. How about hysterectomies?

A. All the time.

Q. Are you familiar with the risks that are involved with those procedures?

A. Clearly, any major surgery in that arena, both from the anesthesia, from the risk of bleeding, from the risk of—anything we do, the risk of bleeding, hemorrhage, infection, trauma to surrounding tissue—that's what we tell every patient every time, because that's what is true.

Q. Doctor, let me ask you to assume that a situation would arise in your practice in which a patient suffered from a serious health condition, and the physician had the option of either performing a hysterectomy, hysterotomy, I think on the one hand or an intact D & X on the other. Would it, ever be appropriate, in those circumstances, to utilize the hysterotomy or hysterectomy?

A. The circumstance I gave you where the patient was before [1164] me, and was actively bleeding intra-abdominally, and I was in her abdomen, that clearly was—the hysterotomy was the appropriate thing to do. Depending on the specific circumstances and cervical dilation and things, if somebody felt they could safely do a D & E, that would be a very unusual set of circumstances. But if that arose, I have people in our hospital who would do a D & E. I don't have any indications I could possibly think of where a D & X would be the thing to do.

Q. Dr. Sprang, is it ever necessary to perform an intact D and X on a living fetus during the second trimester, in your opinion?

A. No.

Q. Why is that?

A. Because there is both induction and D & E. And if somebody could describe for me some situation where, and I can't think of one, and nobody else can think of one, but say somebody came up with one, I would simply say at this point in time, there is so much information either trying to get the cord first, which the people in our hospital always do first, is try to cut the cord. And, obviously, the baby would exsanguinate or intrafetal Digoxin, or potassium chloride. It is becoming more and more common in the medical community and, in fact, in my institution, within the last couple of weeks. Before, they used to just offer [1165] it to a patient if they wanted or kind of asked for it. Now it's the policy, at least at Northwestern Health Care, that every patient who under goes a D & E, has an injection and they use potassium chloride. They could have chosen Digoxin as well. The beauty of potassium chloride is you can easily—and they are very good at what they do. They can easily see the heart. You inject a 20 gauge, 18-, 20-, 22- gauge needle directly into where the chambers of the heart. You can inject two and three C Cs, a couple of drops of potassium chloride, and there is immediate cessation of the heart. You don't wait, you don't do anything with the needle in there. You're watching the heart beat with the ultrasound, and it stops. So you have immediate death. You take out the needle and do what you need to do, and in that case, you're always doing it on a dead fetus, so you are never doing an intact D & X. Because intact D & X is on a

live fetus. Another clear distinction, which I should have said before, major distinction, and from ethical points of view, a major distinction which I hope you get to, if you kill the fetus in the uterus, none of these issues are there. You know, it's within the body of the mother. The mother has the rate of her own body. She can control it. When the fetus is killed outside the body, in the delivery process, that ethical questions are raised. And the Supreme * * *.

* * * * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

No. 4:03CV3385

LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., AND JILL L. VIBHAKAR, M.D., ON BEHALF OF THEMSELVES AND THE PATIENTS THEY SERVE, PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES, AND HIS EMPLOYEES, AGENTS AND SUCCESSORS IN OFFICE, DEFENDANT

Apr. 7, 2004
9:00 a.m.

Volume 7

TRANSCRIPT OF TRIAL PROCEEDINGS, BEFORE THE HONORABLE RICHARD G. KOPF, UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFFS: PRISCILLA J. SMITH
JANET CREPPS
NAN E. STRAUSS
Attorneys at Law
Center for Reproductive Rights
120 Wall Street, 14th Flr.
New York, New York 10005

JERRY M. HUG
Attorney at Law
1823 Harney Street
Suite 1004
Omaha, Nebraska 68102

FOR DEFENDANT: ANTHONY J. COPPOLINO
TERRY M. HENRY
PREEYA M. NORONHA
ANDREW I. WARDEN
U.S. Department of Justice
Civil Division – Federal
Programs Branch
P.O. Box 883
Washington, D.C. 20044

* * * * *

[1254]

THE COURT: Good morning.

MR. COPPOLINO: Good morning, Your Honor.

THE COURT: Counsel, you may proceed.

MR. COPPOLINO: Your Honor, the defendant calls Dr. Curtis Cook.

DR. CURTIS COOK, DEFENDANT'S WITNESS, SWORN

THE COURT: You may inquire.

[Dr. Curtis Cook—Direct]

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Good morning. Good morning, Dr. Cook. Would you tell the Court, please, who you are, where you're from, and what you do for a living?

A. My name is Dr. Curtis Cook. I'm a maternal fetal specialist from Grand Rapids, Michigan.

Q. Dr. Cook, I put in front of you on the witness stand a copy of Defendant's Exhibit 527. Would you please take a look at that. Could you identify that document for the Court?

A. This is a document of my curriculum vitae that I believe was most recently updated in January of this year.

Q. And did you create this document, Dr. Cook?

A. I did.

Q. And does it accurately reflect your education, work experience, publications, the organizations that you are a [1255] member of?

A. It does.

MR. COPPOLINO: Your Honor, the Government moves to admit into evidence Defendant's Exhibit 527.

MS. SMITH: No objection.

THE COURT: Received.

BY MR. COPPOLINO:

Q. Dr. Cook, what is your area of medical specialty?

A. I'm a maternal fetal medicine specialist, board certified in maternal fetal medicine. I'm also a obstetrician-gynecologist, and board certified in obstetrics and gynecology. In general, you would describe my position as taking care of women with complicated pregnancies.

Q. You anticipated my next question. Could you tell the Court, if there is anything more to say, what is a maternal fetal specialist?

A. Maternal fetal medicine specialist is someone who has done an additional length of training, beyond their obstetrics and gynecology residency, to learn to care for complicated pregnancies that may include complications that are medical complications for the fetus or medical complications for the mother.

Q. Is that also referred to as a perinatologist?

A. Yes. There are different terms that are utilized. Perinatology, meaning around the time of birth. High risk [1256] obstetrics, but generally the official term we use is maternal fetal medicine specialist.

Q. Doctor, where do you practice medicine?

A. In Grand Rapids, Michigan, and some other locations in west Michigan.

Q. Are you licensed to practice in Michigan?

A. I am.

Q. Who are you employed by?

A. I'm employed by Spectrum Health, which is a large health care organization predominantly in western Michigan.

Q. Are you associated with a medical school?

A. I am. I have an academic appointment with the Michigan State College of Human Medicine.

Q. And what is your—if there is a title or position that you hold in connection with Michigan State?

A. I'm Associate Clinical Professor in the Department of Obstetrics and Gynecology.

Q. So is it correct to say that in addition to your clinical duties at Spectrum Health, do you teach medical students and residents?

A. That's correct.

Q. Where did you go to medical school, Doctor?

A. I graduated from Indiana University School of Medicine.

Q. What year did you graduate?

A. 1989.

[1257]

Q. And where did you do your residency?

A. I did my residency at what was then called Butterworth Hospital, and is subsequently now part of Spectrum Health.

Q. Could you just explain briefly how a medical student goes on to be an OB/GYN?

A. After successful completion of your medical school training, you then enter a four-year residency program in obstetrics and gynecology. And then in the situation of maternal medicine, there is an additional training period called your fellowship training period in complicated pregnancies, which is currently a three-year training commitment.

Q. And where did you do your residency, Doctor?

A. I did my residency at Butterworth Hospital in Grand Rapids.

Q. At that time, were you working on OB/GYN matters?

A. At that time, I was training in obstetrics and gynecology, yes.

Q. Your Fellowship, Doctor, where was that?

A. My Fellowship training in maternal fetal medicine was at the University of Louisville in Kentucky.

Q. Did there come a time after the completion of your fellowship training that you returned to Grand Rapids and Butterworth Hospital?

A. I did return in Grand Rapids in 1995 where I have [1258] subsequently practiced maternal fetal medicine.

Q. What course of instruction did you go through to become a maternal fetal medical specialist?

A. Well, there is a series of both clinical and didactic experiences that are required, but for myself, it was a six-year training program; four years of obstetrics and gynecology, and two years of maternal fetal medicine. Subsequent to my training, they have increased the commitment of training to seven years with four years of the residency and three years of a Fellowship.

Q. And just to be a little bit more specific, in your Fellowship on maternal fetal medicine, what kinds of things are you exposed to, in order to prepare you to become a board certified maternal fetal medicine specialist?

A. We are expected to have experience and expertise in a wide variety of both medical and surgical complications for both the mother an her unborn child or children, which would include ultrasound capability, would include managing surgical complications that may arise for either the fetus or the mother, doing certain intrauterine surgical procedures on a fetus, things of that nature.

Q. Doctor, what positions do you currently hold in Spectrum Health, and could you tell us what they entail?

A. Currently, I'm the Associate Director for Maternal Fetal Medicine at Spectrum Health, which means I have certain * * *.

* * * * *

[1260] sorry. Surgical and medical management in the field of clinical obstetrics and sometimes gynecology as well. We teach them surgical techniques, indications for surgery, management of complications of surgery, and in the same sort of things in the medical realm, all in relation to generally obstetrics but also some gynecology.

Q. What settings do you teach the medical students in at Michigan State?

A. They participate in our didactic lectures. They participate in our on-the-floor clinical management teaching or teaching of clinical management of patients. They participate in our operating rooms where we also are doing clinical teaching. They also come over to our office where they experience some of the ambulatory medical management and surgical management of complicated pregnancies.

Q. Could you describe what you teach medical students with reference to the various trimesters of pregnancy?

A. Well, there are multiple issues that we teach, that we have to touch on during the course of their education. Everything from fetal development issues to maternal physiologic changes of pregnancy. We also have to deal with the management of complications in

all three trimesters, and those complications can include delivery in all three trimesters, or management of complications of deliveries in all three trimesters.

* * * * *

[1263]

A. Again, there are a variety of procedures that we perform on the fetus as part of being a maternal fetal medicine specialist. They may include procedures that are sampling procedures, where we are taking material from a fetus, maybe fluid or tissue from various body cavities; from the chest, the abdomen. We may be putting shunts into a fetus in order to bypass an obstruction. We may be doing transfusions into the baby for certain anemia situations. We sometimes treat the baby directly with certain types of medications to facilitate our ability to do other surgical procedures. So there is a number of different biopsies, samplings, training, treatments that we do.

Q. Are any of those procedures that you perform on living fetuses life saving procedures for the fetus?

A. Many of them are, yes.

Q. Which ones are those?

A. Most specifically, when we are transfusing a fetus that has severe anemia, without those transfusions the fetus would not be able to survive the pregnancy.

Q. Do you also treat women for complications of abortion?

A. We do.

Q. Would you describe for the Court what types of complications you treat for women that have had abortions?

A. If we see a patient in the immediate period of time after an attempted abortion, it's typically a treatment [1264] regarding some sort of inadvertent perforation, or laceration, or incomplete termination where there is retained fetal parts. If we are treating a longer term or delayed complication of a prior termination of pregnancy, that usually entails issues related to cervical weakness or cervical incompetence or premature labor.

Q. Doctor, does your practice involve the termination of pregnancy before term?

A. Sometimes it does.

Q. And, first of all, let me just ask, what's the most common method of pregnancy termination prior to term that you utilize?

A. In our practice, because of the nature of the patients that we see and the gestational age at which they are referred, it's predominantly through the method of medical induction.

Q. Why is that?

A. Well, for a number of reasons. One is many of the indications are babies with certain types of lethal fetal abnormalities. They are typically diagnosed by mid trimester ultrasound and don't come to our attention until generally later than 16 to 18, and often, later than 20 weeks gestation. In addition, if it is a suspected fetal abnormality, we frequently want to have a complete fetus for pathologic evaluation after delivery. Also, many of the [1265] patients that we see also have

underlying maternal medical complications that mandate that we try to deliver them in as controlled a situation as possible, using as normal a process as possible for the delivery.

Q. Okay. Now, Doctor, in addition to medical induction, have you had occasion to perform abortion by other methods?

A. There have been some rare instances where we have been involved in other types of procedures including surgical evacuation of the uterus in the second trimester.

Q. And why did you describe it as rare instances that you were performing surgical evacuation?

A. Because, again, most of the ones we see are later gestational ages, or we feel that the preferable way to deliver them is by medical induction. There are a few instances where we have been involved in surgical delivery of a second trimester fetus because at that time, that would be the optimal route for delivery.

Q. Have you had occasion to have to terminate a pregnancy on a fetus that is living?

A. I have been involved in cases where we have had to complete the pregnancy on a still, at that time, living fetus, prior to viability.

Q. And could you describe to the Court the different circumstances in which you might proceed in which you have to terminate a pregnancy both pre- and post-viability.

* * * * *

[1272]

A. I'm familiar with suction, aspiration or curettage procedures. I'm familiar with other mid trimester surgical evacuation procedures such as D & E. I'm familiar with medical induction of labor, predominantly through the use of Prostaglandins. And I'm also familiar with the use of other surgical techniques such as hysterotomy.

Q. Let's just briefly go through those. Could you just give us your description and understanding of what the suction curettage method is, when it applies and what kind of a method that is?

A. The suction curettage method is typically a vacuum aspiration method, usually reserved for the first trimester of pregnancy, meaning the fetuses that are 12 weeks gestation or less, and it involves minimal dilation of the cervix with the passing of a cannula, whereby you are then applying a vacuum suction in order to evacuate the intrauterine contents. There may be a follow-up sharp curettage done with an instrument following this procedure as well.

Q. And have you had occasion to perform that procedure?

A. I have.

Q. And in what circumstances?

A. Typically, in the situation of a pregnancy that's termed a missed abortion, which means a spontaneous loss of a fetus or a spontaneous miscarriage, where they have not passed the [1273] tissue on their own.

Q. Now, you mentioned the D & E method abortion. First of all, what does D & E stand for?

A. Stands for dilation and evacuation.

Q. Have you ever performed a D & E abortion?

A. I have.

Q. First of all, can you describe that procedure as you understand it?

A. Typically, it's a procedure that requires more cervical dilation, in order to remove the fetus, which typically is dismembered in the process of that procedure. And following the procedure, the dismembered parts are then assimilated and accounted for to assure there has been completion of the procedure.

Q. Why don't we just go to the judge's question. Have you ever performed—Tell us what your experience is in performing D & Es both in the circumstances of a living fetus or a fetus that is not living?

A. First, my experience is not a large number of cases predominantly because of the timing at which patients are referred to me and the nature of the patient that is referred to me, but there have been some rare instances where the clinical situation would necessitate a surgical evacuation, and I have been involved in some of those cases. I have also been involved in some cases where I'm providing [1274] ultrasound support or guidance for another practitioner who is doing the procedure, typically because there has been a failure of another procedure.

Q. If you can estimate it, Doctor, have you ever performed a D & E on a living fetus?

A. To my knowledge, I have not directly been the one performing the procedure on a fetus that is living at the time of D & E. I have either assisted or participated in cases where the baby was recently living but

not living at the time of the procedure. And there are some cases where I may providing ultrasound guidance where we are not exactly sure when the fetus had a loss of the heart rate.

Q. And, again, why don't you typically perform D & Es on living fetuses?

A. Well, mostly because it's not my treatment of choice, because of the other clinical circumstances that are going on at that time. But if the case arose where we felt that it was in the mother's best health interest to end the pregnancy, and we could not do it safely as in the manner of a labor induction, then I have experience doing the D & E technique and would do that, if the clinical situation necessitated that, in order to preserve the health of the mother.

Q. All right. Now, have you had occasion to utilize the D & E technique to empty the uterus on a fetus that's already [1275] dead?

A. I have.

Q. And could you describe to the Court your experiences of the numbers of times you have had occasion to do that, either in a year, or per year, or over the course of your career?

A. Again, that's not very commonly needed procedure in our practice, so I might do it one time a year or less. But there have been some clinical situations that are relatively unique to our practice where that has been the method that we have felt has been the most effective method for emptying the uterus.

Q. Getting back to the process of the D & E, could you just describe a little more specifically how fetal

parts are grasped and removed during the course of a D & E?

A. In years prior to ultrasound guidance, it was done in a more blind fashion by first having some period of time of cervical preparation or dilation, in order to allow passing of instruments which are typically large grasping-type instruments, where they try to grasp whatever portion of the fetus they can get ahold of. And they try to drag it down through the cervix, while at the same time, trying to disarticulate those portions of the fetus so they can deliver the fetus through a smaller opening.

Q. And did I hear you correctly to say the operator [1276] employs some sort of traction in removing the fetal part in a D & E?

A. That is correct.

Q. And traction against specifically what?

A. Typically, against the cervix.

Q. And I hope this is a clear question, but what is the result of a D & E, in terms of the state of the fetus at the conclusion of the procedure?

A. Well, typically the fetus is delivered in portions that are disarticulated or nonintact. And following the end of the procedure, there should be confirmation that all of the fetal parts are present, including the thorax and all four extremities. But most importantly, the after coming head, which can sometimes be the most difficult part of the procedure.

Q. Doctor, could you describe for the Court what the nature of fetal tissue is like in prior to 20 weeks?

A. Well, prior to 20 weeks, the general nature of the tissue is much more fragile than we observe, for instance, at 24 weeks and beyond. The skin is much more easily disrupted, the fetus bruises much more easily, inadvertent disarticulations or trauma can occur much more ea

Q. Can you explain to the Court how it is that you know what the nature of fetal tissue is both before and after 20 weeks, since you don't perform D & Es on all that many * * *.

* * * * *

[1299] he deals with every particular high risk pregnancy, but we'll establish that.

BY MR. COPPOLINO:

Q. Do you have an opinion as to whether the partial-birth abortion procedure is ever medically necessary to deal with the health interests of mothers facing high risk pregnancies?

A. I do have an opinion on that matter.

Q. What is your opinion?

A. My opinion is that it is never medically necessary, in order to safely evacuate a uterus, and it is my opinion that it is not even necessarily the preferred method, that it may entail unforeseen and unnecessary risk both immediately and in the future, and I feel that this is the situation, whether we are dealing with a healthy mother and a healthy fetus, or a sick mother and/or a sick fetus.

Q. And do you have an opinion, Doctor, as to whether the partial-birth abortion procedure presents

risks to the woman undergoing it as compared to other methods of termination of pregnancy?

A. Yes. I believe that the various elements as described by practitioners of this procedure include elements that I would say have an unacceptable either immediate or potential later risk associated with them.

Q. All right. Let's take those one at a time, Doctor. Why [1300] are you of the view that partial-birth abortion is never medically necessary to care for women with complicated pregnancies?

A. Well, it's my opinion that is the situation because this procedure doesn't add anything to existing medical options that are already safely and readily available for the mother for ending her pregnancy or evacuating her uterus. In addition, they involve some elements that I think have potential increased risks that are not necessary, and I also don't see that in any way facilitates our ability to empty a uterus in that it is still a multiple-day procedure, in less than an optimally-monitored situation. And I think it's an inhumane way to deliver a fetus.

Q. How long have you been providing care to women with complicated pregnancies, Doctor?

A. Well, I started taking care of obstetrical-type patients in the late 80s and started seeing complicated pregnancies from that first day. But I have been treating more exclusively complicated pregnancies since 1993.

Q. Have you ever experienced the clinical situation in which the partial-birth abortion procedure has ever been, in your view, required or necessary?

A. I have not.

Q. Now, but you testified earlier that it is sometimes necessary to terminate a pregnancy for maternal health [1301] reasons; is that correct?

A. That is correct.

Q. First of all, is that common?

A. It is not very common, even in our practice where we see only complicated pregnancies.

Q. Why isn't it common?

A. Well, because, most times, mother's can be adequately supported through their pregnancy, or we can at least get them to the point where the fetus has the chance for survival, and then we can help her to deliver or separate herself from her fetus so that her recovery process can be initiated and the fetus can still have a reasonable chance for survival.

Q. What conditions have you seen or treated in a pregnant woman that you determined were prior to the pregnancy be terminated—prior to—let's just leave it there, that you require the pregnancy be terminated?

A. Well, most commonly, they would be situations that are unique to the pregnancy such as an infection or heavy bleeding with the pregnancy. Or they may be elements of an exacerbation or worsening of an underlying preexisting medical condition such as hypertension, heart disease, diabetes, or other unique elements of pregnancy such as severe pre-eclampsia or some of its variants such as HELLP Syndrome and things of that nature.

[1302]

Q. Would you explain why it may be necessary to terminate a pregnancy prematurely because of these conditions?

A. Most of those conditions are either unique to pregnancy or exacerbated by the pregnancy. So in order to facilitate the mother's recovery from that situation, we need to work toward ending the pregnancy or delivering the fetus. It doesn't require that we destroy the fetus. It just requires that the fetus and the mother are separated from one another, and that the placenta is delivered in order to facilitate the recovery process for the mother.

Q. Now, when you need to terminate a pregnancy for one of these maternal health conditions, do you proceed differently depending on whether the fetus is pre or post-viable?

A. We do. If it is a fetus that is beyond the period of time where we think the baby has a reasonable chance for survival, then we will be doing more continual fetal monitoring, and we will attempt to deliver in a manner that is both safe for the mother and least traumatic for the fetus. If it's a situation where the fetus has a lethal fetal anomaly or is pre-viable, we may not be continually monitoring the fetus, and we may not be considering as much the fetal contributions to the delivery method or route as much as we would consider the maternal implications of those methods.

Q. Okay. So specifically for a fetus that you've [1303] determined has a chance to survive outside the mother, how do you approach a pregnancy termination in that circumstance?

A. Well, it is always our preference to try to deliver vaginally by utilizing, again, a normal laboring process

because it's most physiologic and generally best tolerated by the mother. And so that's how we would generally proceed. In some situations where we need to deliver prematurely, the fetus may be also experiencing complications such as a situation of preeclampsia where the baby may not be growing adequately or getting adequate nutrition; where the baby may not tolerate a vaginal delivery. In that situation, we would then do an operative delivery such as a cesarean delivery in order to facilitate maternal recovery and to allow the least traumatic method of delivery of the fetus.

Q. And how do you proceed differently for a fetus that you've determined has no chance of survival outside the mother?

A. Well, then we are less concerned about the fetal tolerance of labor in the vaginal delivery process specifically. So we would put a greater emphasis on trying to deliver vaginally if there aren't fetal concerns involved.

Q. Doctor, could you explain how you evaluate a maternal [1304] health condition during pregnancy in order to determine whether and when the pregnancy should end?

A. Well, that's obviously a complicated assessment that includes a variety of physical exam and history collection. It involves certain laboratory tests and radiographic studies. It generally involves a consultation of some of our other subspecialty colleagues, such as the neonatal physicians or potentially other subspecialists such as cardiologists, oncologists, people of that nature.

Q. And this might be too general a question, but let's give it a shot. When does something move from being merely a health problem that the woman is facing

during pregnancy to something that you consider to be potentially more serious that could actually cause serious damage to her health or may even jeopardize her life?

A. Yes. That is a good question. Generally, the situation that we would recommend that the pregnancy needs to be delivered would be a situation where we feel the fetus has either attained a gestational age where survival is very likely and the fetus would do well, and we won't accept any level of abnormality in the pregnancy. Or in the earlier gestational ages, if we recommend early delivery, it's because we feel we can no longer control the underlying medical or surgical condition with the treatment modalities that are available to us at that time.

[1305]

Q. Is it the case, Doctor, that if the mother was—if the fetus was close to viability but not yet there, if you had an—if you were able to, consistent with her health, would you try to stabilize her condition or treat her condition in order to buy time to get the fetus past viability?

A. We would, mostly at the behest of the mothers who are willing to do almost anything they can to facilitate the safe delivery of their fetus. We would never put a mother in jeopardy to enhance a good fetal outcome, but it is commonly the case where we can support a mother through some critical weeks of the pregnancy in order to get a good outcome for both the mother and the fetus because both of them are our patients.

Q. Now, in dealing with a situation where you have a pregnant woman with a serious medical condition, and

you're facing the need to possibly terminate the pregnancy early, I would like you to give the Court a sentence of how often do you have to do this prior to viability, versus how often are you able to get the mother past viability and deliver both—and deliver the baby successfully?

A. Well, it has become much easier in the last few years for us to be able to attain a level of viability because the viability line keeps shifting backwards. And even during the course of my career, there has been a marked improvement in survival at 23, 24, and 25, and 26 weeks gestation. So [1306] it's easier for us to reach that level. In addition, our medical technology has grown to the point where we can support very complicated pregnancies for longer periods of time than we could in the past. Complications such as underlying malignancy, cardiovascular disease, what-have-you. So it's not very often that we truly have to deliver a baby pre-viability because of severity of a mother's condition. It does come up on a regular basis in our practice because of the kind of patients we deal with, but it doesn't come up as frequently as it used to.

Q. Um-hm. When a pregnancy has to be ended prematurely because of a maternal health condition of the kind that you treat, is it ever necessary to take a destructive act against the fetus directly in order to protect the health interests of the mother?

A. No. All that is required for recovery of the mother is for separation of the fetus and placenta from her system so that she can start the recovery process. There is nothing inherent in the destruction of the fetus that starts to facilitate that process.

Q. But I take it you also want to utilize the safest method of termination possible in the circumstance where you have to terminate the fetus pre-viability?

A. Yes, in the world of maternal fetal medicine, we, of course, have both as patients, both the mother and the [1307] fetus. And our goal is always to have an optimal outcome for both. In the rare situation where we feel we cannot optimize the fetal outcome, we would never jeopardize maternal health for that reason, and her health concerns would always be the predominant concern at that point. So we would then proceed to deliver her in the method that we think is safest and most well tolerated by her, but frequently, we can achieve it—a goal where we can do a delivery process that is optimal for both the mother and the fetus.

Q. In your opinion, Doctor, would there ever be a medical need to use the partial-birth abortion or D & X procedure to terminate a pregnancy, specifically because of a particular type of maternal health condition that the woman has during a pregnancy?

A. I know of no such condition, and we have been discussing this same issue for many years, and I have never heard anyone propose a condition, I think, that would warrant that situation.

Q. I'm going to give you—I'm going to talk about some specific maternal health conditions, Doctor. You mentioned, I believe, a condition called preeclampsia, and if you didn't, could you at least tell us what is preeclampsia?

A. Preeclampsia is a medical condition unique to human pregnancy, generally starting after 20 weeks gestation, or [1308] actually, by definition, starting after 20 weeks gestation that usually involves high blood

pressure or hypertension in the mother as well as proteinuria or protein in her urine, and may involve other clinical signs such as edema or swelling as well.

Q. Doctor, could preeclampsia ever evolve to a point that it could be an indication to terminate a pregnancy?

A. That is correct.

Q. Could that ever occur prior to the point at which the fetus is viable?

A. Yes, this is true.

Q. Okay. And in your opinion, would the partial-birth abortion D & X procedure ever be necessary to terminate a pregnancy because of a severe threatening preeclampsia condition?

A. It would not.

Q. And why not?

A. Because there are other better options available that, again, are readily accessible to most practitioners that would allow a safer completion of the delivery process, while still maintaining the option for the best outcome for the fetus.

Q. How would you proceed to deal—to terminate a pregnancy for a woman suffering from preeclampsia to such an extent you felt the pregnancy had to be terminated before [1309] viability?

A. Well, in the situation that you're speaking of, it would be for pregnancies between 20 and 23 weeks gestation. And most commonly, what we would do, because you are so near the point of viability or peri-viable, we would do our best to support the mother during those critical weeks while administering certain medications to her that would improve the outcome for

the fetus, and do our best to try to get her to the point of viability, and then proceed with either a vaginal delivery or cesarean delivery, based upon the clinical scenario. If it's a situation where the mother is rapidly deteriorating and we are not able to control the situation, and she's still less than 23 weeks, we generally would then proceed with a medical induction of labor with careful monitoring of the mother's health status.

Q. At your opinion, in that stage of gestation you just described for this condition between 20 and 23 weeks, and for this condition, preeclampsia, would a surgical termination of the pregnancy be indicated?

A. No. I would be very concerned about that. One of the Hallmarks of preeclampsia is something that has a long-term, but it's a microangiopathic process which means it's an abnormality of the vascular system which predisposes, as part of that, to low platelets or a problem with adequate clotting of blood; also a propensity to having more [1310] bleeding, and there are other things that happen in preeclampsia that make a woman less tolerable of bleeding complications specifically. So I would be very concerned about doing a surgical evacuation of a uterus in the setting of severe preeclampsia in that 20- to 23-week range.

Q. All right, Doctor. I think you may have mentioned in your expert report another condition called renal disease. Could you tell us what types of—what a renal disease is in the context of complicated pregnancy?

A. Well, renal disease refers to disease of the kidney, which may either be the primary disease focus, or it may be a secondary manifestation of another underly-

ing disease process such as diabetes or hypertension. But if we have the situation where the woman has a deteriorating renal condition that we feel is secondary to the pregnancy, then we are in the same sort of situation we described with preeclampsia, trying first to achieve viability and maximize the good fetal outcome. And in the situation where that is not possible, and her health status is rapidly deteriorating despite our best efforts, then we would recommend trying to proceed with as physiologic a process as possible which would be a medical induction of labor.

Q. So is it correct to say, Doctor, a renal condition could deteriorate to the point where it might be an indication for termination of pregnancy, prior to fetal viability?

[1311]

A. Yes, that would be the case.

Q. In that case, Doctor, in your opinion, would the partial-birth abortion D & X procedure ever be necessary to terminate a pregnancy, specifically because of the nature of the renal disease?

A. It would not.

Q. Why not?

A. Again, because there are other safer and readily available options that are present. In addition, a woman that has an underlying severe renal condition is also not a woman who can tolerate significant blood loss, loss of fluid, need for fluid replacement, and other situations that would be, I think, just too high a risk to proceed with a surgical evacuation in the late second trimester.

Q. All right, Doctor. Now, another category of potential complications in a pregnancy is cardiac disease as listed in your report. I want to ask you about that. What types of cardiac diseases would so complicate a pregnancy that there would be a need to terminate the pregnancy prior to the due date?

A. Well, we see women with a large number of cardiac conditions mostly because the other areas of medical management have improved so much. And so we see many more children born with congenital heart disease, repaired or nonrepaired. They are now surviving to child-bearing ages. [1312] We see women having children later in age than before. So we see women that are pregnant after having prior myocardial infarctions or heart attacks. We see women with certain types of heart rhythm problems that could not be controlled in years past that are now controlled, and they can achieve not only a child-bearing age but a health status that would allow pregnancy. So we see a number of cardiac conditions, but the number that would actually necessitate an early delivery pre-viability is relatively small; includes predominantly those people that have significant pulmonary hypertension or shunting of blood in the opposite direction of its usual shunting, so that they are having deoxygenation problems or problems delivering adequate oxygen to their tissues. There are also other conditions such as the condition of the dilation of the aorta as part of something called Marfan's Syndrome. That if it reaches a certain critical level, dilation is at risk for aortic dissection or disruption, which would be life threatening to the mother. These are all some specific conditions that may warrant early termination of pregnancy.

Q. And let me just run through those. The pulmonary condition, would that—could that be an indication for terminating the pregnancy prior to viability?

A. Yes, it could be.

Q. And the shunting of the blood condition that you [1313] described, could that also be a condition for terminating the pregnancy prior to viability?

A. Yes.

Q. Marfan's Syndrome, could that be a indication for terminating the pregnancy prior to viability?

A. If it involved significant aortic dilation.

Q. Let's take them one at a time again. Well, let me just—I'm going to ask you a single question and ask you to address those three conditions. In your opinion, would the partial-birth abortion or D & X procedure ever be medically necessary to terminate a pregnancy for those three cardiac conditions you just mentioned, the pulmonary condition, the shunting condition, and the Marfan's Syndrome?

A. No, I don't believe it is ever medically necessary in any of those conditions, nor do I believe it's even the preferable way to go or even and equivalent option. I'm concerned about doing, again, a surgical procedure late in the second trimester where the risk for perforation, bleeding, infection, and other complications that would not be well tolerated by a mother with those sort of conditions would be just unacceptable to me. In addition, we also want to carefully manage and monitor even things as simple as her pain sensation and her release of certain types of endogenous, or within her own system, hormone stress responses that may further complicate her underlying cardiac [1314] condi-

tions. So we want to proceed in a method that is as physiologic as normal, as controlled and as gentle a process as possible, specifically in the area of complicated cardiovascular disease.

Q. Is it the case, however, Doctor, that an induction procedure could impose some physiological stress on a woman undergoing it?

A. Absolutely. We generally have these patients meet with our anesthesia colleagues prior to proceeding with these procedures, and there are specific steps that we take using issues such as epidural anesthesia, careful cardiovascular monitoring, careful evaluation of input and output in the form of fluids for the patient, all to maintain as normal as physiologic and as gentle a process as possible, and that can be done much better in a controlled, monitored medical induction, you know, procedure.

Q. Why wouldn't a surgical termination of that abortion for pulmonary heart condition, or shunting condition, or the Marfan's Syndrome be a procedure that would be less stressful on the woman and, therefore, potentially more favorable given her heart condition?

A. Well, the gestational ages at which we are discussing in this later second trimester are much more difficult procedures to do a surgical evacuation on; do involve greater risk for, again, bleeding, perforation, infection [1315] and other things that would not be well tolerated by a mother with these underlying conditions. In addition, there are some really practical issues related to having a woman who is awake and alert, yet is receiving adequate pain control, in a patient with an underlying cardiac condition, meaning by that that they

want her to be able to report to us if she's having chest pain, shortness of breath, other symptoms that need to be addressed. Things you can't do if a patient is intubated and not communicating with you.

Q. What is peri-partum cardiomyopathy?

A. It refers to a condition that seems to be exacerbated, if not caused alone by the pregnancy, the hallmark of which is a dilated heart with less than adequate contractility or function. So a woman goes into a heart failure type of situation most commonly diagnosed in the immediate post-partum period, meaning after delivery.

Q. I see. So is that a condition that typically implicates the need to terminate a pregnancy prior to term?

A. It could. It oftentimes doesn't present itself until after delivery. Although, there are underlying cardiomyopathies caused by other situations such as hypertension, and illicit drug use and things of that nature, which could potentially indicate the need for an early termination of pregnancy, if it was a preexisting condition.

[1316]

Q. And if that indication arose where there was a need to terminate the pregnancy prior to viability for cardiomyopathy condition, in your opinion, would partial-birth abortion D & X procedure ever be necessary to do that?

A. Again, the optimal method would be utilizing something that would have a lower risk for complication, a greater ability for monitoring and assessment, and something that would utilize a variation on a normal physiologic process.

Q. And in that circumstance, for the cardiomyopathy condition, you would, again, proceed by medical induction?

A. I would.

Q. Doctor, what is HELLP syndrome, H-E-L-L-P. Is that the correct acronym?

A. That is correct.

Q. Would you tell Court what that is?

A. It's an acronym for a clinical spectrum that basically is a variant of severe preeclampsia, the hallmark of which is hemolysis or destruction of red blood cells, and then elevated liver enzymes and low platelets.

Q. Is it a potentially serious health condition for a pregnant woman?

A. It is a potentially life threatening condition, although reversible by the process of continuing to complete her delivery.

[1317]

Q. Have you treated a pregnant woman with this condition?

A. Many times.

Q. By the way, the other conditions we have talked about, the cardiac conditions, the renal conditions, have you treated women with the conditions you have discussed this morning?

A. I have treated women with all those conditions.

Q. Severe preeclampsia as well?

A. Yes, that's a very common referral to our practice.

Q. All right. Now, could HELLP Syndrome—I believe you said it could be an indication for termination of pregnancy prior to viability?

A. This is correct.

Q. In your opinion, would the partial-birth abortion D & X procedure ever be necessary to terminate a pregnancy with this condition?

A. It would not.

Q. And why not?

A. Again, for very similar reasons to the other situations we discussed. That there are safer, readily available options. There are better options, I think, in order to maintain a normal, you know, variant of a physiologic process. Specifically with HELLP Syndrome, the platelet counts are quite low and the risk for bleeding complications is quite high. So anything that we think would potentially [1318] increase the risk for a bleeding complication, perforation, hemorrhage, what have you, would be something we would want to avoid at all costs.

Q. Doctor, what about a patient with leukemia? Have you ever—first of all, have you ever treated a pregnant woman who had leukemia?

A. I have treated pregnant women with active lymphoma during pregnancy, and I have treated women who had leukemia in the past, but I'm not sure I have taken care of a woman who had active leukemia during her pregnancy.

Q. Would leukemia potentially be an indication for early termination of pregnancy?

A. Very rarely, but potentially, if there is a new diagnosis of leukemia, leukemia is treated most commonly by a combination of certain therapeutic agents, some of which can be modified and still given during the course of the pregnancy, some of which would not be well tolerated during the pregnancy. So in a rare instance where they feel the best treatment is something that the fetus would not tolerate and they feel the need to institute therapy immediately, then it could arise. But I would think that that would be, you know, a very rare situation.

Q. I should have asked you for the uninitiated—What is leukemia.

A. Leukemia is a malignancy of the blood system, [1319] specifically the white blood system, where there is an over production of abnormal or malignant white blood cells; the treatment of which is predominantly in the form of medical management or chemotherapy, often times with a combination of chemotherapeutic agents.

Q. In those circumstances where it might be an indication for early termination of a pregnancy, because of the need to provide the woman the medication necessary to treat that condition, in your opinion, would the partial-birth abortion D & X procedure ever be medically necessary to terminate that pregnancy?

A. It would not.

Q. And why not?

A. Again, for some of the same reasons; other safer alternatives available. It—Also leukemia can have, as part of its manifestation, a replacement of other blood products lines, specifically platelets. So they can have also very low platelets. And in addition, their blood

counts can be depressed significantly if they are receiving chemotherapy. So those are reasons that we would also want to avoid specifically anything that we think would increase the risk for hemorrhage, bleeding and perforation.

Q. Those are reasons you would want to avoid surgical termination?

A. This is correct.

[1320]

Q. Okay. What is it about the surgical process that would exacerbate those conditions?

A. Again, in these peri-viable periods of time 20 to 23 weeks, the D & E is a much more complicated procedure, and larger fetus, more need for manipulation, more potential for perforation, bleeding and hemorrhage.

Q. Doctor, what is sepsis?

A. Sepsis is a clinical state in which there is an infection that has involved the body systemically that is moved from a local infection to being a more global or systemic infection.

Q. Could a women have an infection of her uterus that would be so severe in her pregnancy that an early termination, prior to viability, would be indicated?

A. Yes.

Q. Have you ever seen or treated such a condition?

A. I have.

Q. All right. In those instances where a woman has a severely infected uterus early in her pregnancy,

would a partial-birth abortion procedure ever be necessary, in your opinion, to terminate that pregnancy?

A. It would not be.

Q. Is there anything specific about the infection condition that you would think a surgical termination, in particular, would be contraindicated?

[1321]

A. Yes. In the situation where we are looking at a severe infection, we oftentimes are trying to intervene before infection continues or migrates or extends beyond the uterus and its contents. So if we have a severe infection limited to the uterus, and it is not responding to our therapies, we would like to try to empty the uterus of that infection as part of the treatment before it gets to the point where there is a systemic infection that is truly life threatening for the mother. One of the concerns about a surgical method is that it would potentially increase the risk for seeding or allowing extension of infection into the general maternal vascular system because of the instrumentation involved, and the risk, again, for bleeding and perforation. So we would not like that contained infection to have access either to her intraabdominal area, peritoneal cavity or to her vascular system.

Q. Is that one of the reasons why you would proceed by medical induction to terminate a pregnancy of a woman who had severe sepsis?

A. Yes. In addition, the body usually responds to a localized infection by trying to expel the uterine contents on their own. So, generally, those people are very easy to get delivered, often times with very minimal assistance, medically.

Q. What about other types of cancer? Let's just say breast [1322] cancer. Have you ever treated a woman who is pregnant and has breast cancer?

A. Yes, I have.

Q. Might it be necessary to terminate a pregnancy of a woman who has breast cancer, prior to her due date?

A. Yes. That is possible. I have treated several women faced with that decision where they were diagnosed in the first trimester, some of which opted to end their pregnancy and start their therapies, some of which opted to continue their pregnancy with a modified therapy or delayed therapy.

Q. What specifically might be the indication for a termination of a pregnancy for a woman who has breast cancer. Is it the medication that she needs?

A. Generally, it's the medication. The pregnancy process, in and of itself, doesn't necessarily, to our knowledge, exacerbate the malignancy or change the long-term course of the malignancy, but it does limit some of our treatment options, whether it's radiation therapy or chemotherapy.

Q. In your opinion, Doctor, in those instances in which it may be necessary to terminate a pregnancy because of the treatment needed for breast cancer, would a partial-birth abortion or D & X procedure ever be necessary, specifically because of the breast cancer and the need to treat it with medication?

A. No, I do not believe it would ever be necessary.

[1323]

Q. And that is because?

A. Well, many of the same reasons women with malignancies of any sort do have, as part of their disease process, commonly severe anemia, and may also have very low platelets and other conditions that, again, would not allow a woman to tolerate a surgical procedure, particularly a riskier surgical procedure, meaning that done at later gestational ages.

Q. I would like to ask you about at least one more, Doctor, and that is have you ever treated a woman who was pregnant that has had a prior scar on her uterus?

A. Many times.

Q. And what's the cause of that? In your experience, what has been the cause of the experience where a woman has a scar on her uterus?

A. A vast majority of the time is because after prior cesarean delivery, a hysterotomy, although we see patients who have this surgical incisions on their uterus, such as removing a uterine fibroid; a procedure called myomectomy.

Q. Have you ever faced a situation where it was necessary to terminate a pregnancy early, a prematurely, let's say—pre- or post-viability, where a woman has had a scar on her uterus?

A. Yes, I have.

Q. Okay. Now taking it post-viability, how would you [1324] proceed?

A. Generally, we would proceed in the same fashion. We would, if there was no scar on the uterus, with the exception that we may choose to use more cervical preparation before the medical induction, and we would probably avoid certain specific types of Prostaglandins in that situation.

Q. Would a prior scar on the uterus ever be a contraindication for a medical induction?

A. No, not an absolute contraindication.

Q. Would it ever be a relative contraindication for induction, a prior scar on the uterus?

A. It could be, depending on what the situation is. Specifically, if a patient has had a known prior uterine rupture or more extensive involvement in the scar on the uterus.

Q. Does a prior scar on the uterus increase the risk for uterine rupture, during a medical induction?

A. Well, a prior scar on the uterus increases your risk for uterine rupture, whether you're in spontaneous labor or whether you're having a medical induction.

Q. And how do you manage that risk when you're performing a pregnancy termination, either pre- or post-viability?

A. Well, generally if they have had one prior low transverse cesarean section incision, which is the vast [1325] majority of incisions, their risk for uterine rupture is about half a percent or one out of 200. So we believe that amount of risk is an acceptable risk in a situation where we were carefully monitoring the mother and had the capability to proceed to other surgical procedures, if necessary, if she does experience a complication.

Q. Would it be safer, in the case of a woman having a prior uterine scar, to perform a surgical termination in order to end the pregnancy?

A. One of the difficulties of having a prior scarred uterus is that you have inherent weakness in the

integrity of the uterine wall which would mean you would be prone for uterine perforation, which is known risk of surgical evacuation of the uterus. So I don't believe necessarily that a surgical procedure allows you to avoid the risk of uterine perforation or uterine rupture.

Q. Prior to fetal viability, if a woman had a scar on her uterus, would there be any point at which you believe a D & E termination would be an acceptable alternative?

A. I think it would be in a situation where you have made a reasonable attempt to try to induce labor with standard Prostaglandins, and in lieu of maybe using excessively higher doses or other types of Prostaglandins, you may elect to do a surgical evacuation in a controlled setting.

MR. COPPOLINO: Your Honor, this would be a good * * *.

* * * * *

[1327] stand, please.

(Dr. Cook resumed the witness stand)

THE COURT: You may proceed.

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Dr. Cook, before the break, we had been discussing a number of specific maternal physical health conditions that could arise during a pregnancy, and I'm not going to ask you about any more specific ones, you may be happy to hear, but I do want to just ask you a couple of wrap-up questions. First, can you think of any maternal physical health complication for which a partial-birth abortion or D & X

procedure would be a medically necessary procedure, prior to fetal viability?

A. Again, I have been involved in this process and these discussions for a number of years and many scenarios have been presented to me, and I have considered many scenarios, and I have yet to come across a single case where I see it's necessary medically or otherwise to do a partial-birth abortion, in order to effectively and efficiently deliver the mother or separate the mother from her fetus. So I'm not aware of any clinical separation that warrants this procedure.

Q. In particular, Doctor, if the maternal health condition was deteriorating rapidly, and you had an emergency where you had to end that pregnancy as quick as possible, would [1328] the partial-birth abortion D & X procedure be appropriate in that circumstance?

A. It would not.

Q. Why not?

A. Again, because of the other available options, both medical and surgical, that have been available for a long period of time, can be done safely. Patients have ready access to those procedures. So that, and the fact that I think this procedure has other unacceptable risks involved.

Q. What about the time that would be involved in treating a woman with an emergent condition? Would you have the time, even if you considered the partial birth abortion procedure to be a relatively safe option, to do it?

A. Well, I have commented in the past that one of the, in my opinion, unreported aspects of the partial birth abortion procedure is that it involves, you know,

at least two days of cervical preparation, prior to doing the procedure, in order to achieve the amount of overt dilation that you need for the cervix in order to complete that particular procedure. So if you are in a time-limited situation, then you would not be able to utilize this procedure.

Q. Now, Doctor, we reviewed a number of situations regarding serious maternal health problems in pregnancy, and whether the D & X partial-birth abortion procedure would ever be necessary to treat them. If you had a situation [1329] where a baby was previable, where the maternal situation—maternal health situation was deteriorating to the point you felt it might jeopardize her life, and you felt the D & E procedure was the most appropriate option to terminate the pregnancy, would you have any moral or ethical objection to performing the D & E procedure in that circumstance?

A. Well, we, oftentimes, have to make difficult decisions in the world of maternal fetal medicine as we are constantly trying to achieve and optimal outcome for both the mother and her child. In the situation where there may be a conflict of interest, we would always choose the mother's interest over the unborn child, meaning we wouldn't sacrifice a mother in order to try to continue a pregnancy. So there could be a scenario that would arise in the early or mid second trimester where we feel the condition had deteriorated to the point we can no longer treat the mother effectively. And if she is in danger, then I would not have an objection or any sort of hesitation to proceed in any manner I felt was necessary in order to deliver her baby and allow her to recover. And if that included D & E on a baby that was still living at that time, then that would be what we would have to do, after, again, care-

ful consideration, consultation with other physicians, consultation with the family.

Q. Doctor, you've testified this morning that you also * * *.

* * * * *

[1334] then I let them do that procedure.

Q. Doctor, where a decision has been made to terminate the pregnancy for a fetal anomaly, in your opinion, is it ever medically necessary to utilize the partial birth abortion D & X procedure because of the specific nature of the anomaly?

A. No, that's not the case. Again, multiple various types of fetal conditions have been proposed that people have suggested would be treated best or potentially only by the procedure partial-birth abortion. And I haven't found that to be the case in any of the proposed cases.

Q. Can you think of one fetal anomaly for which termination of the pregnancy by the D & X procedure would be required?

A. I cannot.

Q. Can you think of any fetal anomaly for which termination of a D & X procedure would be the most appropriate option, because of the nature of the fetal anomaly?

A. In the case of hydrocephaly, I would like to address that.

Q. Can you tell the Court what hydrocephaly is?

A. Hydrocephaly refers to the distention of the ventricular system in the baby's brain, which is the fluid filled canal system within the central nervous

system of a fetus. And if that canal system gets overly distended, secondary to either a blockage or an overproduction of cerebral spinal fluid, then that leads to a condition called hydrocephaly; which, [1335] in its most extreme form, can lead to actual macrocephaly, or a large fetal head.

Q. In that case, what can be done to safely deliver the woman?

A. Well, most cases of hydrocephalus don't have macrocephaly associated with it. They have large distended ventricles but not a large fetal head. In that situation, you would proceed, as you would in any other, induction of labor. But if it's a situation where they have macrocephaly, then what we would do is an intrauterine procedure similar to a procedure they would do ex utero, meaning we would decompress the ventricular system by placing a needle aseptically, surgically into the distended ventricular system, and aspirating off some of that fluid, just like they do in the neonatal period, in order to make the head size small enough to be able to allow vaginal delivery. Now, there are some situations where if a patient declines that procedure, then we would proceed with a cesarean delivery.

Q. In this particular condition of hydrocephaly, would there typically be a desire or need to have fetal brain material in order to conduct pathologic testing?

A. Yes. Many of the abnormalities that we see do involve the central nervous system, and they do have recurrence risk, and they can be difficult to distinguish by just an [1336] anti-needle ultrasound. So pathology is sort of a big tool we would utilize in those situations. So having an intact central nervous system would be critical if the concern was for the central nervous

system. If the concern was that the baby had abnormal chromosomes or something of that nature, then the intactness of the central nervous system is less critical.

Q. And would the partial-birth abortion procedure be suitable for pathology testing for anomalies for which brain tissue would be for pathology?

A. No. I can't even see how they would be able to interpret that tissue, if, indeed, the primary problem is in the central nervous system.

Q. If an intact fetus is deemed necessary or desirable for pathological testing, is there a safe alternative to partial-birth abortion D & X procedure?

A. Yes. It would be either an induction of labor or potential cesarean delivery.

Q. I would like you to look at Defendant's Exhibit 608, and let me assist you in finding that. Doctor, have you seen this document before?

A. I have.

Q. Did you review this document in connection with preparing your expert report in this indicates?

A. I did.

* * * * *

[1341] Again, they have very good recovery and catch-up growth ex utero, outside the uterus.

Q. What about placental cysts? Is that on the list as well?

A. I don't see it here immediately. I have seen it before on the list. I just don't see it right now. But I see placental insufficiency. It's a long list. But placental cyst, in an of itself, is a benign finding seen fre-

quently. Doesn't threaten maternal health. Doesn't have long-term implications for the fetus. Another one I see now, which I think I have mentioned before, which makes up a very large number of his indications are polyhydramnios or increased amniotic fluid volumes. Again, no risk necessarily to the fetus, if no other underlying abnormalities are seen. And, again, just a common finding in pregnancy.

Q. Thank you, Doctor. Doctor, I would like to talk about the safety issue surrounding the partial birth abortion D & X procedure. Are you of the view that—what is your view with respect to simply the safety of the partial birth abortion procedure, in and of itself, as a method of terminating pregnancy?

A. Well, whenever we talk about using surgical methods late in the second trimester, early third trimester, that always concerns me, because those are known to be riskier procedures, greater risk for bleeding, infection, [1342] perforation. But specifically with this procedure, there are elements that I'm very concerned about. I'm concerned about the marked-over distension of the cervix which is much greater than is used in other procedures. I'm concerned not only about immediate issues like, you know, discomfort for the patient and unsupervised monitoring of the patient during her two-day pre-procedure induction, but I'm also concerned about what implications that may have for her later ability to continue to maintain a pregnancy to a point of viability with subsequent pregnancies. I'm concerned about other specific elements of the procedure like the concept of turning a baby in the uterus, which also increases the risk for maternal injury, and generally is abandoned in the practice of modern obstetrics. I'm concerned about the method in which a

baby's life is taken, when it's virtually completely delivered, then has its, you know, brains sucked out of its head.

Q. To your knowledge, have there been any studies evaluating the medical safety of the partial-birth abortion D & X procedure? Are you aware of any?

A. I'm not aware of any studies that are comparison studies that are published to date looking at specifically safety issues, either in the short term or the long term.

Q. Now, I just showed you this morning the papers by Dr. Haskell and Dr. McMahon. Why aren't they studies that * * *.

* * * * *

[1356] with this procedure was the potential long-term complications it might have on cervical incompetence; is that correct?

A. Cervical incompetence and pre-term delivery.

Q. Would you explain what your concern is with the procedure in connection with cervical incompetence and pre-term delivery?

A. Well, there is an increasing body of evidence that supports that people that have had a prior termination of pregnancy are at increased risk for subsequent preterm deliveries and potentially low birth weight infants. And those studies are done predominantly on people that have procedures done in the first trimester where there is very little manipulation necessary for the cervix in the form of dilation. So some data would suggest the risks are higher when you're doing mid term procedures, or mid trimester procedures. I believe that is related to the amount of manipulation necessary in the amount of dilation to the cervix. So if

you take that to an even a greater extreme where there is a massive over-dilation of the cervix, then I have an even greater concern about the potential integrity of the cervix and the ability to maintain a pregnancy to term in the future.

Q. What is your understanding of the process of dilation for the D & X procedure that causes you to have these * * *.

* * * * *

[1362]

MR. COPPOLINO: Ready to break, Your Honor.

THE COURT: The doctor's answer, and I appreciate that the terms are used may be used differently. I did not understand the last answer to apply specifically to abortions accomplished by the induction method, although the word induced was used in the doctor's answer. I understood his answer to be broader than induction abortions.

MR. COPPOLINO: Yes, Your Honor. Perhaps I can clarify that when we return. The term induced, I think, is referring to various methods of abortion, but we can clarify that when we return.

THE COURT: All right. We'll stand in recess until 1:30. Doctor, you may step down, sir.

THE WITNESS: Thank you.

(Recess from 11:59 to 1:30 p.m.; all parties present)

THE COURT: Doctor, if you will come forward, please, and take a seat in the witness stand.

(Dr. Cook resumed the witness stand)

THE COURT: Counsel, you may inquire.

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Dr. Cook, before the break, I was asking you some questions about potential long-term consequences of the D & X procedure, and I want to just go over some of that very briefly. Is there any existing data on the effect of abortion that believe might indicate a [1363] problem with the intact D & E procedure or D & X procedure in terms of long-term consequences?

A. Well, I think I mentioned before, there is an increasing body of evidence regarding the potential risk of induced abortion. And, again, when I use that term, I'm distinguishing it from spontaneous abortion or miscarriage. So abortions that are caused by care providers, there is an increasing body of evidence that that subset of patients is at increased risk with subsequent pregnancies for both pre-term delivery, mostly secondary to cervical incompetence issues, and also potentially at risk for low birth weight infants. The existing data has looked predominantly at the earlier terminations of pregnancy where there is less cervical manipulation. And so my concern is, and there is data to suggest this, that the later procedures, where there is even a greater amount of cervical manipulation, would lead to potentially even a greater concern, specifically for pre-term labor, specifically pre-term labor related to cervical weakness issues.

Q. When you use the term induced abortion, that's including all methods of abortion that are provided by the physician; is that correct?

A. Correct.

Q. All right. And how does that data that exists concerning potential complications of abortion relate to

[1364] your concerns with respect to the D & X procedure?

A. Well, one of the hallmarks or distinguishing features of the D & X procedure is this, again, super distension or over distension of the cervix beyond that which is usually done for typical second trimester procedures like D & E, and certainly beyond that done for first trimester procedures like suction curettage. So if the concerning data is with the issue of pre-term delivery, and that data exists even for people that have first trimester abortions, then I'm concerned the risk would be even greater with those that had later abortions, specifically by a technique that would involve marked or overdistension of the cervix.

Q. Doctor, turning to another safety concern. To the extent that the D & X partial-birth abortion procedure involves an internal podalic version of the fetus to the breech position, do you have an opinion as to the safety of that procedure?

A. I do. It is concerning, whenever you talk about trying to turn an infant within the womb, that you can increase the risk for maternal trauma in doing that, and it's generally not part of current obstetrical practice to still utilize that technique. That was an older technique used years ago for different situations and has been sort of resurrected for this particular procedure. But I think there are inherent risks associated with it that have been recognized [1365] by obstetricians that practice other methods of abortion and other methods of just delivering of infants, and, I believe, even practitioners of this particular procedure—there has been some concern about doing internal podalic version.

Q. Doctor, would the risks of the internal podalic version be less in mid second trimester or mid trimester as opposed to at term, in delivering a baby at term?

A. I'm not certain that the risk changes that much, based upon the gestational age, because it's the concept of being within the uterus in a somewhat blind fashion and manipulating a fetus within that closed environment that is the risk.

Q. And what is the risk of that procedure?

A. Well, perforation of the uterus, trauma to the uterus, and then all the things that go along with that, including risks of bleeding and infection.

Q. With respect to the issue of uterine perforation, would the use of ultrasound offer some protection against perforation in performing a D & E in which the fetus is dismembered?

A. Well, certainly I think ultrasound is always advantageous whenever we are doing any procedure within the uterus, because you're working with a window into the womb, so-to-speak. You're not doing your procedure as blindly, so you can identify specifically in D & E where the head may be [1366] or certain extremity may be, and you don't have to be grasping around within the uterus blindly with your forceps. You can go right to the area you're trying to target.

Q. What would be your opinion of performing a D & E or a D & X without the use of ultrasound?

A. Well, I think it would be not practicing contemporary obstetrics. It's a tool that is part of our routine armamentarium and should be utilized in any procedures where you are doing intrauterine manipulations.

We use it for therapies targeted at the fetus. I even use it where we have a situation where there may be a retained placental tissue after a medical induction, abortion or procedure, and the baby has been expelled but the placenta remains. If we have to do D & C or dilatation and curettage, we do that under ultrasound guidance to reduce our risk of perforations or other complication.

Q. For those who would assert they performed D & E or D & X procedures safely without ultrasound, because of the experience that they have gained, would you say that they are practicing a safe procedure?

A. Well, you certainly can accomplish it without the benefit of ultrasound, and it was done that way for years when ultrasound was not available. And experience is helpful in that regard, but I would say that you're not availing yourself of all the resources that are available, [1367] and you're not performing it as safely as you could be performing it in this day and age.

Q. Doctor, do you have an opinion as to whether the safety of the D & X procedure should be evaluated by reliance on data demonstrating the safety of the D & E procedure?

A. Well, I do have concerns about that that I believe I mentioned that it is difficult to compare a traditional D & E procedure, most of which are still done at earlier gestational ages than most of the D & X procedures. I think it's difficult to compare those two from a risk assessment standpoint, because we know the risks are tied greatly to gestational age. The higher gestational age, the greater the risk. I think, again, the more accurate comparison is what truly happens as it is

proposed now, medical induction as proposed D & X procedure beyond 20 weeks of gestation.

Q. Do you have an opinion as to whether the safety of the D & X procedure, as compared to induction procedures, medical induction procedures, should be evaluated by reliance on data comparing the D & E procedure to prior methods of induction?

A. Well, that's problematic as well. You always want to be comparing groups that are comparable and are contemporary. And the problem with looking at data that is several decades old, utilizing old induction techniques, specifically installation techniques, and comparing that to D & E or even [1368] worse by extrapolation D & X would be really a stretch. It's just not an accurate comparison. You need to compare contemporary induction methods with Prostaglandins administered orally, vaginally, intramuscularly. Compare that group with what would be a more appropriate comparison group, the D & X procedure as it's been described and performed.

Q. What is your understanding of the statistics that existed—that exist, based on prior studies, as to the relative safety of the D & E procedure with prior methods of installation induction?

A. Well, again, data now several decades old would demonstrate that D & E is considered generally a less complicated procedure than installation techniques of induction, up until about 16, or maybe 16 to 18 weeks gestation. After that, they are comparable risk.

Q. Doctor, do you believe that current methods of induction, termination in the second trimester, have improved over the installation methods of induction that have been previously used?

A. I do. This is an area of active research and development. Instead of, again, using installation of saline, hypertonic saline or Prostaglandins, we now administer new and different types of Prostaglandins by different routes, constantly studying different formulations * * *.

* * * * *

[Dr. Curtis Cook—Cross]

[1418] practitioners of D & E that I'm aware of may place two, three or four dilators.

Q. So what you meant to say, the dilation involves up to ten times the amount of laminaria; is that right?

A. This is correct.

Q. It's your belief, isn't it, Doctor, that a D & E between 22 and 24 weeks poses significant risks for maternal mortality; is that right?

A. I believe it poses greater risk than those done at the earlier procedures. Earlier gestational ages, I'm sorry.

Q. You believe it poses significant risks, don't you?

A. I do.

Q. Doctor, sometimes when you have performed an induction abortion previously, you have had to perform a D & E; isn't that right?

A. That is correct.

Q. And it's your opinion that in a case where you're performing an induction abortion, and the fetus's head became stuck, and you were forced to perform a D & E to remove the fetus, that a Duhrsen's incision would be a safer procedure in the case of fetal head entrapment

than collapsing the fetal skull with forceps; isn't that right?

A. Could I have us just repeat the question one more time? I'm sorry.

Q. It's your opinion, Doctor, that in a case where you're [1419] performing an a induction abortion, and the fetus's head became stuck, and you were forced to perform a D & E to remove the fetus that a Duhrsen's incision would be a safer procedure, in the case of fetal head entrapment, than would collapsing the fetal skull with forceps?

A. Well, there are several elements there that I don't agree with in your statement and some that I do. When we are doing an induction, and the after coming head becomes trapped, we don't do a D & E procedure. We have multiple options available in order to try to facilitate the remaining portion of the baby to be delivered, meaning the after coming head And those options include medical treatment of the mother with agents that help relax the uterus, like nitroglycerin is one that we use. One of the other options would be to place after coming forceps on the head. Another option would be to make Duhrsen incisions to create more room for the cervix. Another option would be to do some sort of crushing procedure on the baby's head or some sort of suctioning or evacuation of the fetal brain contents. Those are all options available. Then if you ask me what I believe are the best options, I believe the best options would be the first three. Medical relaxation of the cervix, forceps for after coming head, or Duhrsen incisions. Did that answer your question?

Q. So if the medical relaxation of the cervix didn't work [1420] and the forceps didn't work, you would do a Duhrsen's incision; is that correct?

A. That's correct.

Q. Can you explain to the Court what a Duhrsen's incision is?

A. A Duhrsen's incision is taking a scissor and making a one to two centimeter cut on the cervix. We usually do it either at 12:00 o'clock, or we'll do it at like 4 or 7:00 o'clock, in order to try to avoid the major blood vessels on the cervix. And then if need be, do a surgical or suturing of that area of after the delivery.

Q. So, for example, if this cup is the cervix, you would make incisions like that? Is that right? Around the top?

A. You would make one incision and see if that—and that frequently is enough to release the after coming head. And then sometimes we don't even need to repair it, because when a woman delivers, she frequently has cervical lacerations as well, in a normal situation. What we do is if it looks like it's bleeding, we tend to repair it. If it looks like it's not bleeding, we tend not to put suture in it just to reduce the risk for adhesion formation and other manipulation.

Q. Doctor, just to clarify, did you say that the com *[sic]* compression would be tried before the Duhrsen's incision or after?

A. In my opinion, it would be a latter choice. It would be [1421] a less favorable choice.

Q. Okay. And, Doctor, do you believe a Duhrsen's incision is more gentle than dilation using osmotic dilators?

A. I do believe that that is the case. It's a single incision that's done in a portion of the cervix with immediate repair.

Q. Doctor, is it part of the natural physiologic process?

A. It is observed frequently as part of the natural physiologic process of labor. We frequently see cervical lacerations in that area.

Q. So it's your contention that a Duhrsen's incision is part of a natural physiological process, because sometimes the cervix tears during delivery?

A. That's exactly what I'm saying.

Q. Okay.

A. In the same location.

Q. So, Doctor, is it your contention that a procedure that causes injury to the cervix 100% of the time, meaning one, two or three, one to two-centimeter long incisions through the cervix, with the resulting scarring that would occur because of stitching, is less likely to cause cervical incompetence than slow dilation using osmotic dilators over a period of one to two days?

A. Well, I'm not sure how to answer that. I don't agree with all of your adjectives. But, yes, I do believe a * * *.

* * * * *

[Dr. Curtis Cook—Redirect]

[1457]

BY MR. COPPOLINO:

Q. And look under where it says item 9, information considered in forming my opinions. In addition to my

extensive experience in maternal fetal medicine and the materials I considered prior to my Congressional testimony, I have specifically considered the following materials in forming the opinions stated in this report. Is that sentence in the expert disclosure report that you provided in this case?

A. It is.

Q. All right. Now, you were asked some questions about induced fetal demise and possible risks of that procedure. Do you perform procedures that involve injections of medications into the uterus?

A. I do.

Q. Do you perform other procedures that involved injections into the uterus?

A. I do. We perform needle procedures into the uterus on a regular basis.

Q. Could you discuss the risk of those procedures?

A. In general, when we are putting a needle into the uterus, there is approximately a 1 in 200 to 1 in 500 chance of losing the pregnancy from a complication such as breaking the bag of water, causing an infection, bleeding, contractions, things of that nature. If we are giving * * *.

* * * * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

No. 4:03CV3385

LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., AND JILL L. VIBHAKAR, M.D., ON BEHALF OF THEMSELVES AND THE PATIENTS THEY SERVE, PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES, AND HIS EMPLOYEES, AGENTS AND SUCCESSORS IN OFFICE, DEFENDANT

Apr. 8, 2004
9:00 a.m.

Volume 8

TRANSCRIPT OF TRIAL PROCEEDINGS, BEFORE THE HONORABLE RICHARD G. KOPF, UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFFS: PRISCILLA J. SMITH
JANET CREPPS
NAN E. STRAUSS
Attorneys at Law
Center for Reproductive Rights
120 Wall Street, 14th Flr.
New York, New York 10005

JERRY M. HUG
Attorney at Law
1823 Harney Street
Suite 1004
Omaha, Nebraska 68102

FOR DEFENDANT: ANTHONY J. COPPOLINO
TERRY M. HENRY
PREEYA M. NORONHA
ANDREW I. WARDEN
U.S. Department of Justice
Civil Division – Federal
Programs Branch
P.O. Box 883
Washington, D.C. 20044

* * * * *

[1486]

MR. COPPOLINO: No objection, Your Honor.

MS. SMITH: No objection.

THE COURT: All right. It's received. With regard to Court's Exhibit 3, I want you to know that I intend to ask the government's OB/GYN witnesses today and tomorrow questions regarding the two scenarios raised by Dr. Darney. All right. Are you ready to proceed?

MR. COPPOLINO: Yes, Your Honor.

THE COURT: You're ready to proceed.

MR. COPPOLINO: Yes.

MR. COPPOLINO: The defendant calls—Your Honor?

THE COURT: That's all right.

MR. COPPOLINO: The defendant calls Dr. Elizabeth Shadigian.

DR. ELIZABETH SHADIGIAN, DEFENDANT'S WITNESS, SWORN

THE COURT: You may inquire.

[Dr. Elizabeth Shadigian—Direct]

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Good morning, Dr. Shadigian. Would you please tell the Court what you do for a living?

A. I would be glad to. My name is Elizabeth Shadigian, and I'm a practicing physician the state of Michigan. I'm an obstetrician-gynecologist, a generalist, and I practice at the University of Michigan as a fulltime faculty member.

Q. Doctor, how long have you been on the faculty of [1487] University of Michigan?

A. I'll be completing my tenth full year this June.

Q. Doctor, I have put on the ledge near you where you're standing, just the first document, please, which is marked as Defendant's Exhibit 529. Do you see that?

A. Yes, I do.

Q. Is this a copy of your CV, Doctor?

A. Yes, it is.

Q. And did you create this document?

A. Yes, I did.

Q. And at the time you prepared it for us, does it accurately reflect your education, work experience and publications?

A. Yes.

MR. COPPOLINO: Your Honor, the Government moves to admit Exhibit 529.

MS. CREPPS: No objection.

THE COURT: Received.

BY MR. COPPOLINO:

Q. Dr. Shadigian, why did you decide to specialize in obstetrics and gynecology?

A. I was very interested in taking care of women throughout their lifetimes, and especially interested in the issues around reproductive health and reproductive choices and why women choose what they do.

* * * * *

[1513] Court. Do you have an opinion as to whether the D & X procedure is ever medically necessary to properly treat pregnant women suffering from high risk medical complications?

A. I know circumstance in which the D & X is medically necessary to treat women with medical problems.

Q. Do you have an opinion as to whether there is a basis on which to conclude that the D & X procedure offers safety advantages to women over other methods of abortion?

A. Since the D & X has never been studied in a formal way in peer review literature, there is no basis to say the D &X is safer than any other procedure.

Q. And so do you have an opinion as to the relative safety of the D & X procedure as compared to the induction method of abortion?

A. Well, there is no sound basis on which to conclude the D & X is safer than medical induction.

Q. Okay. I would like to talk first about the medical necessity of partial-birth abortion, your opinion in connection with that. I believe you testified earlier this morning that it is sometimes necessary to terminate a pregnancy for maternal health reasons; is that correct?

A. Yes.

Q. And you may have said this already, but just describe to the Court how common that actually occurs with reference to [1514] both pre- and post-viability?

A. Post-viability, there are several times that we need to induce labor, and that's a very common thing that obstetricians/gynecologists learn in their training, how to do that safely for babies at different gestational ages. It's uncommon to find a mom who has such a complication in the second trimester that it actually necessitates termination of the pregnancy. But the two I take care of most frequently are the chorioamnionitis and the severe preeclampsia.

Q. Why don't we, then, just briefly restate for the record what those two conditions are. I want to ask you about your experience terminating pregnancy for those conditions. Let's start with severe preeclampsia.

A. Severe preeclampsia is a medical condition that is specific to pregnancy. We don't see it outside of pregnancy, where a woman's liver is affected, where a woman's platelets are affected, and where a woman can get swollen, and have their blood pressure go very high. And in those situations, a woman can start getting so sick that she's at risk of hemorrhaging and dying from the actual medical condition.

Q. Chorioamnionitis?

A. Chorioamnionitis, again, is an infection in the fluid around the baby, the baby itself, and it can extend into the [1515] mother's's *[sic]* uterus, and then into the mother. So that it, in fact, affects both the baby and the mom.

Q. Now, when you are faced with a need to terminate a presentation because of maternal health complication, is that situation approached differently depending on whether the baby is pre or post-viable?

A. In the situation in the late second trimester, we basically don't do anything different. We don't try to make the baby die but we accept that the baby could die as a normal part of this physiological process of terminating the pregnancy.

Q. When the fetus—When you have judged that the fetus has no chance of survival outside pregnancy, is there any difference in the actual method of induction?

A. We can use higher dose medications that may cause the uterus to have a higher rate of both rupture, and it also may be a quicker process if we use higher doses of medications.

Q. And, Doctor, you personally have had to terminate a pregnancy on a living fetus you knew was not likely to survive the termination; is that correct?

A. Yes.

Q. How do you evaluate maternal health conditions during a pregnancy to determine whether and when you should end the pregnancy because of a severe maternal complication?

[1516]

A. Those are tricky situations to make those sort of hair line decisions. But basically we look at a lot of different medical factors. So it's not enough that a woman would have just premature rupture of membranes, say, as a precursor to the chorioamnionitis. We actually have to find physical signs and symptoms. So the uterus has to be tender, the woman has to have a fever. It's not good enough just, for example, the membranes are ruptured. So we have to see that certain criteria are fulfilled. And in the severe preeclampsia, it's not enough just that the blood pressure is high. We can manage blood pressure independent. But when we see the liver being affected, the kidneys being affected, the platelets, when we see other organ systems being affected by the process, then we make the call that it's affecting the mother so much that she's in danger.

Q. In circumstances in which the baby is potentially post-viable, is your approach to try to deliver the baby and then turn the baby over to neonatologists for what they can do?

A. We try to deliver the baby in the safest way to give the baby the most chance of surviving if the baby is in the viability range.

Q. Now, in all these circumstances in which you have terminated pregnancy prematurely, you have used the medical induction method?

[1517]

A. Yes.

Q. When a pregnancy has to be ended pre-viability for a maternal health reason, is it ever necessary to take a destructive act directly against the fetus in order to protect the health interests of the mother?

A. I have never needed to use such an act.

Q. And why not?

A. It's just not necessary.

Q. What is necessary to serve the health interests of the mother when she needs her pregnancy to end pre-viability?

A. The most important thing is ending the pregnancy which means delivering the baby and the placenta. Once that's accomplished, then the mom will get well spontaneously.

Q. In your opinion, Doctor, would there ever be a medical need to use the D & X procedure to terminate a pregnancy, specifically because of a particular type of health condition that the mother is facing in the pregnancy?

A. I can't think of a situation.

Q. Are there, in your opinions, safe and effective ways to terminate a pregnancy for maternal health reasons without the D & X procedure?

A. Yes. We have the disarticulation D & E procedure, and we have the medical induction procedure with many different kinds of medicines that have both been well studied.

Q. Would a D & X procedure ever be an appropriate procedure [1518] to terminate a pregnancy in the circumstance in which maternal health is deteriorating rapidly?

A. No, that would be a circumstance that it would not be good, because it takes so many days to treat the cervix ahead of time and get the body prepared for the actual procedure itself.

Q. I would like to turn back to the subject of fetal anomalies. You testified you had some involvement with that. What happens when one of your patients is diagnosed with a fetal anomaly?

A. When I get the ultrasound report, many times I almost get it at the same time they are doing it. The radiologist will call me. It's our practice that after the ultrasound, the woman comes up to my office and talks to me or my nurse practitioner. So in those situations, I explain what the anomaly is. I explain if it's a kind of what we call fixable or something that we can treat after the baby is born or even during the course of the pregnancy. And then tell them what the likely outcome is. In addition to that, I think it's always in one of these situations that it's complicated. I most generally get a consultation from our maternal fetal medicine colleague, so they can give their opinion to the patient. Many times after that, they want to call me back and see me again or go over things again, because I do have a long-term relationship with most of my * * *.

* * * * *

[1525]

THE COURT: I'm not being critical. I just didn't know.

MR. COPPOLINO: She has reviewed it, but I don't know if I'm going to inquire of that. She hadn't examined it.

THE COURT: I'm not being critical. I just wasn't certain how those things were being handled. I didn't know if she refused to sign it.

THE COURT: No, she's signed it.

THE COURT: Okay. Thank you. That's all I wanted.

(End of side bar)

THE COURT: Pardon me for interrupting, Doctor. I just wanted to ask the lawyers a legal question. And I'm sorry that I interrupted counsel's interrogation. Go ahead, counsel.

BY MR. COPPOLINO:

Q. I would like to then ask you about a couple of specific assertions as to the safety of the procedure, the D & X procedure. For example, it has been asserted the D & X procedure offers a safety advantage because it involves fewer instrument passes and involves the extraction of fewer sharp fetal fragments. What is your view as to whether that is a sufficient basis on which to evaluate the safety of this procedure?

A. Well, that's a very good theory that may describe what [1526] might happen. I don't know if that's actually true, if it's actually safer to pull the baby though the cervix. It actually involves more dilation. On the other side, I could say, well, the cervix is more dilated. You're pulling the baby through rather than letting a physiological process happen. So for every example that people can say they think this is safer, because there is less passes, there is another way you can look at it that it might be less safe, because the cervix is dilated differently or more than in a medical induction.

Q. Do you agree, Doctor, that specifically with respect to sharp fetal fragments, that removing the fetus intact would reduce the risk of laceration or perforation as a result of sharp bony fragments?

A. It should.

Q. Would you agree that—that the procedure, as designed, does have fewer instrument passes than a dismemberment D & E procedure?

A. Yes, it does have less passes.

Q. Do those, in your opinion, do those potential benefits of the procedure provide the whole picture as to the safety of the procedure?

A. It doesn't to me, and it doesn't because of both short-term complications and long-term complications. Many of the people performing the D & X procedure don't actually [1527] see the patients back later, so they don't actually know if they had complications outside a certain number of—a certain number of hours that they may be observing the patient. So it's hard to say what those outcomes would be.

Q. What's your basis for that last assertion as to the follow-up of the abortion practitioners with their patients?

A. Well, there have been several studies. One I quote specifically which is the Picker study from 1999, and they actually asked women about the quality of their abortion care, because this is such an important issue. And, in fact, it turns out that only about 29% of women actually follow up with their abortion provider afterwards. So it's hard for me to understand how abortion providers, in quotes, know their complications if they don't even see their patients back later.

Q. I believe you testified you have reviewed Dr. Haskell's 1992 paper, the *National Abortion Federation Regarding the D & X Procedure*?

A. Yes, I have.

Q. Would you agree that in that paper, Dr. Haskell reported on the results of cases he had undertaken to date using that procedure and that he had found no complications?

A. That's what he said.

Q. Okay. Isn't that a case review that provides some evidence of the procedure's safety?

[1528]

A. Well, the problem I have with Dr. Haskell's report is he said there weren't complications, but he actually never called the patients to find out. He doesn't describe finding out actually about complications. These are just ones that he knows about from his practice.

Q. Let's just assume for a moment that his conclusions with respect to complications are accurate. Isn't it the case that understanding the safety of a procedure starts with case reviews such as the kind Dr. Haskell presented to the National Abortion Federation?

A. Certainly, we do start with case reviews and correlations. We look, at first, to see new procedures by a short case review.

Q. In your opinion, is it sufficient to rely on such self-reported case reviews of physicians who are reporting a procedure and evaluating the safety of the procedure?

A. It's not enough. It's not sufficient.

Q. Why not?

A. Because the person has an invested interest in their, in quotes, new technique they designed them-

selves. They want to—they have a feeling and desire that they want it to be safer. And they have no other comparison group that they use to compare the two groups, if there isn't one.

Q. What about if a physician who is performing this procedure talks and confers and meets with other physicians [1529] that he knows perform this procedure, and, collectively, it's their experience that the procedure is safe. I'm referring to the D & X procedure. Isn't that common experience an indication as to the safety of the procedure?

A. Again, these are the very initial steps people should take to discuss in academic settings or national meetings about a new procedure. But it's the very first step in evaluating procedures. After that happens, there is a series of evidence-based studies that need to happen for us to make any conclusions about the general safety or unsafety of a procedure.

Q. Doctor, now this Court has heard some testimony that there are now some medical schools in the United States purportedly starting to teach the D & X procedure. And assuming that's true, wouldn't that be some indication that the procedure has certain potential safety advantages?

A. I don't think it says anything about safety.

Q. Why not?

A. Because it doesn't evaluate safety. Just because I talk to a group of students about a personal experience I have doesn't mean that it's the way it should be done.

Q. Just hold on for one second, Doctor.

A. Um-hm.

Q. I would just like to talk about some of the specific concerns that you have with the D & X procedure itself, and [1530] as sort of a foundation for that, I would like you to just describe what your understanding is of how dilation is typically achieved for the D & X procedure.

A. Dilation is typically achieved over a set of two days where laminaria or osmotic dilators are placed in the cervix. Sometimes the cervix needs to be straightened out before those are placed. Sometimes they can be placed directly. And then overnight the dilators expand, the cervix dilates more. A woman comes back the next day. They put even more dilators in and let those expand. And then on the following day, a procedure such as the D & E is then—or D & X is then started.

Q. I may have missed this if you said this, and I apologize, but is it your understanding Misoprostol can be used in conjunction with the dilation process?

A. Yes, Misoprostol is now being used by many practitioners in conjunction with laminaria.

Q. In the process of dilation necessary for the performance of a D & X procedure have consequences on a woman's health?

A. Could you restate that question?

Q. Could the process of dilation for the D & X procedure, in your opinion, have any consequences on a woman's health, short-term or long-term?

A. Yes. How many dilators are put in, if they are put in gently or forced into the cervix. Also, we know we can put [1531] dilators in the wrong place. Sometimes the cervix may be stenotic or have some scar

tissue on there. You can create a false tract, if you are not careful. All the things that actually manipulate a woman's body, such as dilation, can have longer-term effects.

Q. Now, in an induction termination, is it the case that the cervix is ultimately dilated to the full size of the fetus coming out? Is that the case?

A. Yes, it is in medical induction.

A. And is that—Why isn't that as potentially as harmful, in your view, as the consequences of the dilation achieved using the methods utilized in the D & X procedure?

A. Again, the D & X procedure uses those laminaria or osmotic dilators whereas in the medical induction procedure, it's only medications that actually have the woman's body start a physiological process of contraction. So there is no laminaria put in in a medical induction, except in very, very rare circumstances.

Q. Just to summarize for the Court, what are your specific concerns with respect to the dilation procedure utilized in the D & X procedure?

A. The concerns are how many times the woman's cervix is dilated over so many days and how far it's dilated with the number of laminaria. So no one has ever done a study to show what the optimum dilation is of the cervix to reduce [1532] trauma. And what we are really talking about is how do we safely reduce trauma to a woman's cervix so they don't go on and have problems with their cervix later.

Q. Doctor, is it your position that there has to be a prospective randomized controlled study in order to evaluate this procedure?

A. There are many different epidemiological studies that could be performed. And they don't all have to be the ones you described. The prospective randomized blinded trial.

Q. What other ways are there for evaluating the safety of this procedure other, than a randomized prospective controlled trial?

A. So there are other studies such as retrospective case controlled studies.

Q. What is a retrospective case-controlled study?

A. That's when there is something called a case and a control. A case is whatever you're trying to study. So in this case, it would be a D & X procedure. Then you decide what kind of control group to compare it to. So you could say I'm going to compare the D & X to a medical induction of labor at the same gestational age. I'm going to compare the D & X to a D & E at the same gestational age. It's where we try to control for many, many factors that would be the same in all the groups but then have one factor different. And then we can head-to-head look at what the differences are * * *.

* * * * *

[1548] the 1990s, 20 to 30 years after legalization. Each shows elevated risk and a dose-response effect.

Q. Doctor, the passages you have just read are from the study that you co-authored here at—what's the exhibit number? At exhibit number?

THE COURT: Should be 531—or pardon me. Yes, 631.

BY MR. COPPOLINO:

Q. At Exhibit 631. Correct, Doctor?

A. Yes.

Q. And the information you just read in the records summarizes part of the results of your research; is that correct?

A. That is correct.

Q. All right. Now, also in the passage you just read, you omitted footnotes numbers, but the numbers in the parentheticals are the references to numbers contained at the article?

A. Yes. It lets other people look at the exact article and know what we are talking about.

Q. What I would like you to do is now that we have read the passage, if you could summarize in your own words here in court what the results of your research were with respect specifically to the relationship between prior abortion and pre-term birth?

[1549]

A. The results show that many of the studies looking at induced abortion and pre-term birth do show an elevation in pre-term birth. What that exactly means is women deliver before 37 weeks of pregnancy more often up to a doubling of that effect, when they have had induced abortion, or what we call abortion here.

Q. Yeah. And is this a risk of pre-term birth a risk that is beyond the normal risk of pre-term birth in a pregnancy?

A. Yes. This is when all the other risk factors for pre-term birth have already been looked at and controlled for during these studies.

Q. All right. Now, in your opinion, what does this—these findings with respect to pre-term birth indicate, with respect to the potential long-term risks of the D & X procedure?

A. The concern is this: The studies we looked at looked mostly at first trimester abortions, and some second trimester, but even with these abortions in these studies, that there is an almost doubling effect of pre-term birth. And now, in the D & X procedure, we are talking a much greater size of the baby, and this baby being pulled though a partially-open cervix such that the mechanism for injury which is purported to be both damage to the cervix, as well as possibly infections. That the potential for damage to the cervix is much greater in a D & X procedure than it * * *.

* * * * *

[1552]

THE COURT: All right. We'll take a 15-minute break now. Doctor, you may stand down.

THE WITNESS: Thank you very much.

(Recess from 10:31 to 10:50 a.m.; all parties present)

THE COURT: Doctor, if you will retake the witness stand, please.

(Dr. Shadigian resumed the witness stand)

THE COURT: You may proceed.

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Doctor, if you still have your article, I would just like to ask you about one additional sentence in the article. It's on page 75, and we'll forego the technology, your Honor. It's just one sentence for this one.

THE COURT: Sure.

BY MR. COPPOLINO:

Q. Page 75, left-hand column, last sentence of the middle paragraph. And I'll just read it, Doctor. It says for those women—Are you with me?

A. Yes.

Q. For those women who choose abortion techniques that, in theory, protect the cervix from trauma such as laminaria or pre-abortion cervical ripening should be used. Is that a sentence in your article, Doctor?

A. Yes.

[1553]

Q. Now, in your opinion, would the use of such techniques reduce or even eliminate the potential long-term risks of pre-term birth from abortion?

A. It may.

Q. And is that something you believe requires further study before we know that?

A. Yes.

Q. Why is that the case?

A. Theoretically, by using laminaria or Misoprostol, these other cervical ripening techniques, we may reduce trauma to the cervix. And that may be the postulated mechanism of why pre-term birth is higher, especially in first trimester abortion where it's not used as often.

Q. Given the stage in gestation when D& X might be performed, and the amount of dilation that's

typically utilized, will we know the answer to that question until the issue is studied?

A. That's the whole point is, we need to study it to know if the laminaria actually help or not.

Q. Doctor, do you have an opinion as to whether the safety of the D & X procedure should be evaulated in some way by reliance on data demonstrating the safety of the D & E procedure?

A. The D & X procedure is really a separate procedure from the D & E, and it cannot be relied upon—the data on D & E * * *.

* * * * *

[Dr. Elizabeth Shadigian—Cross]

[1563] than induction after 20 weeks?

A. It depends on what you mean by body of opinion. If you could define that, maybe I could explain.

Q. Well, let me go back a step then. When I asked you if you believed that there was a substantial body of medical opinion that induction is safer after—safer than D & E after 20 weeks, and you responded yes, what were you referring to?

A. I was referring to the literature search I did and the review of the articles that I did. And so it was my opinion, plus the opinion of others that did review articles, that brought that to light.

Q. All right. So it's your synthesis of the information that's out there that leads you to conclude that there is a substantial body of medical opinion?

A. Yes.

Q. Doctor, do you agree that the safest and most appropriate abortion procedure for a particular woman depends, in part, on the gestational age of the fetus?

A. Yes.

Q. And that the safest and most appropriate abortion procedure depends, in part, on the woman's health?

A. Yes, it may.

Q. And that the safest and most appropriate abortion procedure for a particular woman depends, in part, on [1564] medical contraindications to a particular procedure or part of a procedure for that woman?

A. Yes.

Q. And do you agree that the safest and most appropriate abortion procedure for a particular woman depends, in part, on her history of gynecological surgery?

A. It may, yes.

Q. And that the safest and most appropriate abortion procedure may also depend, in part, on the training, skill and experience of the physician performing the abortion?

A. It may.

Q. You would agree, wouldn't you, Doctor, even if two procedures are statistically similar in terms of risk, the safety for each particular woman depends on her individual circumstances?

A. Yes.

Q. Doctor, just to go back through some of your earlier testimony. You do not perform abortions on live

fetuses except when it's your belief the mother will die if the pregnancy is not terminated; is that correct?

A. That's correct.

Q. That is, luckily, a very rare occurrence; is that right?

A. Yes.

Q. And your best estimate is that you have had to terminate a pregnancy in that circumstance between 20 to 40 times in [1565] your career?

A. Yes.

Q. And in every case in which that was necessary where the fetus was alive, you did that by induction and not D & E; is that correct?

A. That is correct, in my practice.

Q. And in your career, you have performed—well, since you have been at the University of Michigan, approximately 10 to 20 D & E procedures; is that correct?

A. I believe that's so. I never counted them.

Q. Okay. And the latest that you will—that you've performed a D & E procedure is approximately 20 weeks.

A. I would say 20 weeks in my residency, and probably up to 17 to 18 weeks in my practice at the University of Michigan.

Q. And in your capacity as a supervising physician, you estimate that you supervise residents doing D & Es zero to two times a year; is that right?

A. That's correct.

Q. And, again, these are—You are supervising is also in cases of fetal demise; is that right?

A. Yes, it would be only in case of fetal demise, because I don't perform any on live babies.

Q. So you wouldn't supervise somebody else doing that?

A. Correct, because I'm considered the practitioner also, and I would be helping if I did it.

[1566]

Q. Okay. And you supervise approximately two to five inductions of labor per year for the purpose of removing a dead fetus; is that right?

A. No, that's not what I said.

Q. Okay. Can we—In the second trimester, can you estimate how many times a year you would supervise a procedure to remove a dead fetus by labor induction?

A. Probably about two or three times per year.

Q. And you have never discussed, I think we are using the term D & X for your testimony. You have never discussed the D & X abortion procedure with Dr. Johnson; is that correct?

A. If we discussed it at all, it may have been in a teaching situation, not one-on-one with somebody else there.

Q. And you have never discussed the D & X procedure with any physician, any other physician who performs it; is that correct?

A. That is correct.

Q. And you have never induced fetal demise by means of a drug administered to kill the fetus; is that correct?

A. That is correct.

Q. At the University of Michigan, among the physicians who perform abortions on live fetuses, the decision whether or not to induce fetal demise, prior to the procedure, is left to the individuals physicians; is that correct?

A. That is correct.

* * * * *

[1574]

Q. Doctor, did I understand your testimony that you do not personally perform amniocentesis on your patients?

A. I did as a resident and as an early faculty member, but now there is a whole unit that just does fetal diagnosis, so I don't now.

Q. So you would refer your patients who needed that to that unit?

A. At the University of Michigan, certainly, yes.

Q. Doctor, when you perform D & C procedures, you use mechanical dilation; is that correct?

A. Yes, I do.

Q. And when you perform vacuum aspiration procedures to remove a dead fetus, you also would use mechanical dilation as needed; is that correct?

A. Yes.

Q. And you have also used laminaria for some of your abortion procedures; is that correct?

A. Yes, I have.

Q. And in some instances, that has included serial laminaria, which by that, I mean more than one insertion of laminaria?

A. That is correct.

Q. And you're also considering for future cases, or maybe at the present time, adding Misoprostol with the laminaria for the D & E procedures that you use?

[1575]

A. Yes.

Q. And you think that may hold safety advantages for the dilation process?

A. It may.

Q. The patients who receive laminaria are allowed to leave and return the next day for the procedure; is that correct?

A. Yes.

Q. Doctor, I think you testified that one of your concerns about the D & X procedure is that the dilation process may apply or result in a different or greater force being applied to the cervix than in an induction procedure; is that correct?

A. I don't think I used those words today.

Q. Is that a correct statement, though, that those are your concerns—Let me restate the question. That the dilation process for D & X may result in a greater or different type of force being applied to the cervix than induction procedures?

A. I think it's not just—May I clarify?

Q. Yes.

A. Thank you. I think the point that I was trying to make—it's not just the dilation that's different and greater, but it's actually the nonphysiological process of bringing the baby through the open cervix that is

different in a medical induction versus a D & E, for example, or D & X— * * *.

* * * * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

No. 4:03CV3385

LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., AND JILL L. VIBHAKAR, M.D., ON BEHALF OF THEMSELVES AND THE PATIENTS THEY SERVE, PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES, AND HIS EMPLOYEES, AGENTS AND SUCCESSORS IN OFFICE, DEFENDANT

Apr. 9, 2004
9:00 a.m.

Volume 9

TRANSCRIPT OF TRIAL PROCEEDINGS, BEFORE THE HONORABLE RICHARD G. KOPF, UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE PLAINTIFFS: PRISCILLA J. SMITH
JANET CREPPS
NAN E. STRAUSS
SUZANNE NOVAK
Attorneys at Law
Center for Reproductive Rights
120 Wall Street, 14th Flr.
New York, New York 10005

JERRY M. HUG
Attorney at Law
1823 Harney Street
Suite 1004
Omaha, Nebraska 68102

FOR DEFENDANT: ANTHONY J. COPPOLINO
TERRY M. HENRY
PREEYA M. NORONHA
ANDREW I. WARDEN
U.S. Department of Justice
Civil Division – Federal
Programs Branch
P.O. Box 883
Washington, D.C. 20044

* * * * *

[1639] further with the appointment of an expert on my own, although I believe I have the full authority to do that. But for both practical reasons and other reasons, it would seem to me that this ought not to be done in this case without the consent of both sides. So at the conclusion of today's proceedings or at the conclusion of these proceedings, whether it's today or Tuesday, I'll be asking you your views on that and you ought to be thinking about it. All right. Is there anything else we should take up at this time?

MS. SMITH: No, Your Honor.

THE COURT: You may call your next witness.

MR. COPPOLINO: Good morning, Your Honor.

THE COURT: Good morning.

MR. COPPOLINO: Your Honor, the defendant calls Dr. Charles Lockwood.

DR. CHARLES LOCKWOOD, DEFENDANT'S WITNESS, SWORN

THE COURT: You may inquire.

[Dr. Charles Lockwood—Direct]

BY MR. COPPOLINO:

Q. Good morning, Dr. Lockwood. Would you please just start by telling the Court who you are and what you do for a living?

A. I'm the Chairman of the Department of Obstetrics, Gynecology and Reproductive Sciences at the Yale University [1640] School of Medicine. By training I'm a maternal fetal medicine specialist.

Q. How long have you held that position at Yale?

A. Since July of 2002.

MR. COPPOLINO: Your Honor, may I approach the witness?

THE COURT: Sure.

BY MR. COPPOLINO:

Q. Dr. Lockwood, I have handed you what's been marked as Defendant's Exhibit 528. If you would just look through that document and tell me if you recognize that document.

A. I do.

Q. And, Doctor, is this a copy of your curriculum vitae?

A. It is.

Q. Is this a true and accurate summary of your educational, professional background as well as your publications and organizations that you belong to?

A. It's a little out-of-date but reasonable.

Q. This document also lists the various publications you have authored or co-authored; is that correct, Doctor?

A. That's correct. That's the part that's a little out-of-date.

MR. COPPOLINO: All right. Defendant moves into evidence Defendant's Exhibit 528.

MS. SMITH: No objection, Your Honor.

[1641]

THE COURT: 528 is received.

BY MR. COPPOLINO:

Q. Doctor, would you describe your duties and responsibilities as the Chair of the Department of OB/GYN at Yale University?

A. I'm charged with maintaining the quality of clinical care that's offered at Yale-New Haven Hospital with full-time and community physicians that are part of the department, overseeing the residency training program and Fellowship training programs that we offer, and in my guise as the professor of the—professor of obstetrics and gynecology at the university, to promote both the teaching program for the medical students as well as our research program.

Q. Doctor, what did you do before assuming your position as Chair of the Department of OB/GYN at Yale?

A. I was Chair of the Department of Obstetrics and Gynecology at the NYU School of Medicine.

Q. How long did you hold that position?

A. From 1995 to 2002.

Q. Would you briefly describe to the Court what your duties and responsibilities were at NYU?

A. They were analogous, but they had a complexity that there were two hospitals; Tish Hospital or the NYU Medical Center and Bellevue Hospital. And so I served there as a Stanley H. Kaplan professor and chair, and as well, Chief of [1642] Obstetrics and Gynecology at Tish Hospital, and the Director of Obstetrics and Gynecology at Bellevue Hospital. And otherwise, my job description would be analogous to that at Yale.

Q. Doctor, where did you receive your medical training?

A. At the University of Pennsylvania.

Q. You graduated on what date?

A. I graduated in 1981.

Q. And, Doctor, where did you perform your residency?

A. At Pennsylvania Hospital.

Q. Could you tell the court which state you're licensed to practice medicine?

A. I'm currently licensed to practice in New Jersey, New York and Connecticut.

Q. And would you remind us of your board certifications, Doctor?

A. I'm board certified in obstetrics and gynecology with special certification in maternal fetal medicine.

Q. What is maternal fetal medicine, Doctor?

A. That is the field of study and clinical activity in obstetrics and gynecology that deals with complicated obstetrical cases, including pregnancies complicated by maternal medical illnesses and obstetrical complications such as premature labor, recurrent miscarriage, pre-eclampsia, and a variety of other conditions as well as [1643] the fetus. And that includes providing diagnosis and therapy for the fetal patient.

Q. Doctor, is that area of specialty sometimes referred to as high-risk obstetrics?

A. It is.

Q. And in that area of specialty, Doctor, that maternal fetal specialist, do you consider both the woman and the fetus to be your patients?

A. I do.

Q. Do you presently have an active medical practice in maternal immediate fetal medicine?

A. I do.

Q. Could you describe that for the Court, please?

A. The department has a maternal fetal medicine practice that cares for patients with medical and obstetrical as well as those whose fetuses have problems. In addition, we provide a very active prenatal diagnosis and treatment service. One of the busiest in the country. And in addition, have an active transfer service where other hospitals will transport critically ill patients, or patients with impending obstetrical problems, and so we care for patients in all three of those venues.

Q. Doctor, your CV appears to reflect you conduct a fair amount of research as well; is that correct?

A. I do.

[1644]

Q. Could you just describe to the Court some of the various topics on which you have published articles and studies?

A. That would take quite sometime. I have occasionally been accused of having very diffuse interests in research. They include prenatal diagnosis and ultrasound, a focus on premature labor, preeclampsia, clotting disorders in pregnancy. I'm, at a basic science level, very interested in endometrial biology, endometrial hemostasis as we call it. Regulates clotting and bleeding in the uterus, and more so in the mother —well, equally so in the mother. And toward that end, have funding currently from the March of Dimes for a prematurity research study and from the National Institute of Health for studies of the long-term effects of progestin only contraceptives inducing abnormal endometrial bleeding, uterine bleeding. It's a problem with that particular form of contraception. And also, into the basic mechanisms that lead to fetal growth restriction. And then in addition to that, I have a grant from a pharmaceutical company to study the effect of their particular hormone on abnormal angiogenesis of the uterus, how vessels form, blood vessels form in the uterus.

Q. So, Doctor, is it fair to say you're familiar with the process of peer review in the publication of studies?

A. Very.

Q. And have many of your own studies been peer reviewed?

[1645]

A. About 150.

Q. Right. Have you ever served as a peer reviewer for other studies?

A. Many times.

Q. Do you recall which journals, offhand, you have served as a peer reviewer for?

A. Many.

Q. How about one or two?

A. Well, *New England Journal of Medicine*, *Lancet*, *Journal of American Medical Association*, *American Journal of Obstetrics and Gynecology*, *Obstetrics and Gynecology*, *Journal of Clinical Endocrinology and Metabolism*, on whose editorial board I serve. Many others, in addition to those.

Q. Are you a member of any professional organizations, Doctor?

A. I am.

Q. Would you indicate a couple of those please?

A. I'm a member of the American College of Obstetrics and Gynecologists, the American Gynecological and Obstetrical Society, on whose council I serve. I'm a member—Well, as parts of that, I'm the Chair of the American Association of Obstetrician and Gynecologist Foundation, which provides a research training grant for young investigators. I serve on the Research Science and Development Program's selection committee that identifies, again, young researchers for [1646] funding. I belong to the Society of Maternal Fetal Medicine, The Society of Gynecological Investigation, which is the leading research organization in our

field where I serve as secretary/treasurer, and previously to that, on the council. The American Institute of Ultrasound in Medicine. The American Medical Association, the County Medical Society in New Haven, The New York Obstetrical Society, The New Haven Obstetrical Society and a variety of other organizations.

Q. To the extent we have missed any, they are listed on your CV; is that correct, Doctor?

A. Yes.

Q. All right. Doctor, I would like to start by asking you somewhat of a broad question, a couple of broad questions. Do you support a woman's right to choose to have an abortion?

A. I do.

Q. Why did you agree to be an expert for the Government in this case?

A. Well, it's a complicated answer, I think. This is, obviously, an extraordinarily complex and delicate matter. I don't think that there really is any other topic in obstetrics, certainly, that is as controversial or as polarizing, as I have detected from my colleagues over the last month, than this particular topic. And beyond my own * * *.

* * * * *

[1653] 13 weeks by dilation and aspiration as I would call it, suction curettage as you might call it. In addition to all of that, obviously, I follow the literature. I have managed many patients with complications of surgical abortion and medical abortion. And as chair, particularly, I attend our obstetrical and gynecological morbidity and mortality conferences where abortion complications are discussed. And in addition to that, I

have performed ultrasounds during abortions to facilitate and avoid, rather, maternal injury, and facilitate the performance of the procedure. And that continues up to the present.

Q. Now, let me ask you a couple of specific follow-up questions, so we give the Court a little more understanding of your abortion expertise. Have you ever provided care to patients who had a miscarriage or spontaneous abortion?

A. I have.

Q. In those circumstances, what method have you used to complete the miscarriage?

A. Suction curettage.

Q. Could you briefly describe for the Court what that method is?

A. Well, it would depend a little bit on the gestational age. It might be performed in the office within a relatively early gestation, in which the patient would receive pre-medication, most often with Motrin, and would [1654] then be prepped and draped, sterile speculum placed in the vagina. The cervix would be washed with Betadine, a tenaculum would be carefully placed on the cervix. A paracervical block would be given, a local anesthetic would be given. The cervix might be minimally dilated and, again, six, seven weeks gestation, a six- or seven-millimeter suction curette would be placed in the uterus and the contents evacuated and the instruments removed, ultrasound confirmed that there were no residual products in the uterus, and the patient would go home, depending on the circumstances, perhaps on Doxycycline, an antibiotic, and additional pain relief, if necessary. And we would send that tissue for, often, for karyotypic analy-

sis to try to figure out whether this was a chromosomal abnormality that caused the loss and a pathology specimen.

Q. Doctor, have you heard the term dilation and evacuation to describe a method of abortion?

A. I have.

Q. I'm first going to ask you if you can briefly describe that method of abortion, and then following that, I'm going to ask you what your own experience is in that method. But first, just briefly, describe the broad outlines of the dilation and evacuation, D & E method of abortion.

A. The actual procedure would very much depend, again, on gestational age, with more advanced gestational age, * * *.

* * * * *

[1661]

A. Probably the majority were patients with retained placental fragments after outpatient abortions at clinics that offer outpatient abortions. In addition, we have had patients with perforations of the uterus who required the certainly reparative surgery or hysterectomy. And we have also seen patients come to the emergency room who have succumbed from those complications. And in the—Certainly, I have seen in the hospital patients develop a chorioamnionitis after medical abortions.

Q. Doctor, when you were at NYU, did you have responsibilities for the abortion services provided at that institution?

A. Yes, as chairman, I did.

Q. Could you just indicate, because I know you mentioned there were a couple of facilities associated with NYU. Where were abortions performed, specifically at NYU, and where did you have responsibility or supervision of those services?

A. There were very few performed at Tish Hospital for a variety of reasons that aren't terribly important at this point. However, there was an active service when I arrived at Bellevue, and it was the mandate of the city hospital system to provide safe and effective abortions. Subsequent administration of mayoral—however one says administration—actually made training a major focus of [1662] the agency's goal rather. And so, in addition, the residency review committee, the RC, requires that abortion training be made available to residents. Merrick College of Obstetrics and Gynecologists supports that notion. I certainly support that concept as well. So for all those motivations, for all those reasons, we sought to create a reproductive choice service at the NYU Department and at Bellevue Hospital, specifically, that would train residents in abortion techniques, and that would also conduct research in not only abortion, but contraception. Toward that end, we garnered a grant from the National Institute of Child Health and Development to be part of their contraceptive network and to do clinical trials in contraception. So we chose—We had already had a family planning director that was quite skilled and very good. We chose a second person to specifically support the abortion service at Bellevue. And so as part of that, we helped organize the service and ensure that there was a location for it to be done; that the ancillary services would be available to support it, and that it would be safe, frankly, and that there wouldn't be obstructionists that

would try to impair its performance, which could potentially be dangerous. And I think it was—with those goals in mind, it was a substantial success.

Q. All right. Now, Doctor, were you the one who was responsible for creating that program?

[1663]

A. I was.

Q. All right.

A. We had funding, I might add, from different sources.

Q. And what steps, briefly, what steps did you take to develop that program? For example, did you hire the director of the program?

A. I did.

Q. Did you hire other personnel involved?

A. Well, she, actually, subsequently hired other individuals.

Q. All right. Did you have any role in deciding the types of abortions that would be performed in that program?

A. No. The hospital had traditionally permitted terminations up to 24 weeks, and although after 20 weeks, there was at least a tradition that the chair would approve the procedure. And we ended up, number one, allowing the director to have a significant discretion, but as viability was approached, the Ethics Committee at Bellevue was involved in adjudicating whether the abortion would be appropriate.

Q. That was after 24 weeks; correct?

A. Well, in that range. Theoretically, in the state of New York, abortions are permissible up to 26 menstrual weeks, 24 weeks post-conception.

Q. Otherwise, was it the case that the director of the [1664] program had the discretion to decide what types of abortions to perform at NYU?

A. Absolutely.

Q. Do you have any understanding of what types of abortion services are currently provided at NYU?

A. I do.

Q. Could you just state what those methods of abortion are for the Court or list them?

A. They include—I'm not sure whether medical abortions with RU 486 are available. Methotrexate was available. MVAs, manual vacuum aspirations. Obviously dilatation and aspiration or suction curettage. D & Es is understood in this context, and intact D & Xs, or what would be termed a partial-birth abortion, in this context.

Q. Do you have an understanding what is meant by the term partial-birth abortion?

A. I do.

Q. Could you just state what your understanding is, what's meant by the term partial-birth abortion?

A. I think multiple definitions, if you will. There is the definition that Congress has created, and there is the definition of the American College of Obstetricians and Gynecologists have used, which I would prefer for clarity purposes to define, and it involves four elements including internal podalic version to a breech position. First, it [1665] would involve cervical ripening for

sometime, perhaps several days, to enhance the degree of cervical dilatation, followed by internal podalic version, delivery of the fetus until the head abuts the cervix, and then evacuation of the uterine contents.

Q. Now, Doctor, I believe you indicated that the D & X—Let me just back up for a second. You mentioned there were several terms involved. Do you understand the terms dilation and extraction, D & X, intact D & E, and partial-birth abortion to be interchangeable?

A. Okay.

Q. Okay. Do you understand that to be the case?

A. I do. I do.

Q. I think for convenience, I'm going to use the phrase D & X, or dilation and extraction today, so there is no confusion, but understand that that term is interchangeable with intact D & E or partial-birth abortion?

A. I do. I do.

Q. I believe you said you understand that the D & X procedure is being performed at NYU; is that correct?

A. That's correct.

Q. When did you first learn the D & X procedure was first being performed at NYU?

A. In preparation for my expert report.

Q. That was approximately late 2003 or early 2004?

[1666]

A. That is correct.

Q. And how did you come to learn that?

A. I contacted the director and asked her for a rough accounting of the number of procedures done in 2002 and the nature of the procedures and various other details about the nature of resident involvement; how many residents recused themselves and so forth.

Q. Do you know whether the D & X procedure was being performed at Bellevue, while you were Chairman of the Department at OB/GYN at NYU?

A. I didn't ask her to break it down specifically, and my assumption is that it was probably being done at the latter part of my chairman position, yeah.

Q. Assuming that is the case, Doctor, how is it that you would not have known or been specifically aware that that procedure was being performed while you were chairman of the department of OB/GYN at NYU?

A. I certainly allowed the director great latitude to perform abortions. I was extremely confident in her clinical skills and ability, and I don't micromanage how the IVF folks perform invitro fertilization, or how the oncologists treat cervical cancer.

Q. Doctor, is there a family planning and reproductive choice program at Yale University?

A. Not formally.

[1667]

Q. Are you planning to develop such a program?

A. We are.

Q. Why are you planning to put—Let me back that up. Are you planning that that program at Yale will conduct academic research?

A. I am.

Q. Are you planning that that program at Yale will publish peer-reviewed studies?

A. I am.

Q. Is dilation and extraction, the D & X procedure, presently performed at Yale University?

A. Not that I'm aware of.

Q. Okay. Would you allow it to be taught at Yale University?

A. Well, it depends on the court proceedings, I would imagine, more than anything else.

Q. If it is, if the outcome of the case is that the enactment passed by Congress that's at issue in this case is not upheld, would you allow the procedure to be taught at Yale University?

A. Yes.

Q. Are you convinced, Doctor, that the D & X procedure is safer than the D & E procedure?

A. Well, I'm not convinced that it's safer.

Q. Do you believe that the D & X procedure has potential [1668] long-term safety concerns?

A. I have some concerns in that direction.

Q. Doctor, does Yale University have a medical residency program?

A. We have—We do have a medical residency and also obstetrical and gynecological residency program.

Q. Is instruction in abortion provided in the residency program?

A. It's available.

Q. What specific methods of abortion are residents taught at Yale University?

A. They have, I believe, access to all forms in a variety of different settings including in the hospital where—generally speaking, abortions occurring later in gestation are performed, as well as in an ambulatory, two ambulatory settings. One, a woman's surgical center where the community physicians perform the bulk of their terminations, and we, at least the last time I checked, had a program with Planned Parenthood, which would make available our interns during, I guess what we would term a selective, where they don't have to do it, but if they are interested, they have some time during one of their medical rotations that they can go to Planned Parenthood and be part of that. And that was very well received last year.

Q. And you have responsibility for supervising the resident [1669] program?

A. I do.

Q. All right. Now, Doctor, since you do not perform D & Es, surgical abortions on live fetuses, why do you keep yourself informed about abortion techniques?

A. I do try to keep myself informed about all the surgical techniques performed at the hospital. I think some of the division directors would complain that I try to keep myself too informed of what we do. And that may be true, but I certainly do, and I—it's part of our regular morbidity and mortality reviews, whenever there are complications. So I need to have some understanding of the procedure and its potential complications.

Q. I would like to ask you some questions specifically about the D & E method of abortion, Doctor. Is a

D & E abortion, in which the fetus is dismembered, a common abortion procedure?

A. It is.

Q. In your view, is it a safe abortion procedure?

A. Safety always being relative, yes.

Q. Do you know how long D & E, involving dismemberment of the fetus, has been practiced in this country?

A. Probably before *Roe* v. *Wade*, but certainly in a reportable fashion since then.

Q. Do you know, Doctor, if the D & E method of abortion * * *.

* * * * *

[1673] Court, specifically, what sources you have looked at. Just list them in which you have come to an understanding of the D & X procedure.

A. Well, from the descriptions made by Haskell and McMahon, also, frankly, from the expert reports and the deposition and testimony of the plaintiffs' experts.

Q. I believe you mentioned the ACOG statement earlier; is that correct?

A. Correct.

Q. All right. Now, how do you understand the D & X, that the D & X procedure is performed?

A. Well, it would depend; very much like the D & E in all respects, except that there is an emphasis on a greater degree of cervical dilatation, and, therefore, serial placement of laminaria and/or use of Cytotec or Misoprostol at the end. And rather than attempting to place the clamp in such a way as to disarticulate the

fetus, the goal here is to remove the fetus intact. And that can be done, obviously, if the fetus is breech by grasping the feet with the clamp and delivering the fetus. And very often, because the head size is larger than the body size, the head will not pass through the cervix and require the uterine—rather, require the intracranial matter tissue to be removed to collapse the skull to allow delivery. And in the case of a vertex presentation, it's possible that the physician may [1674] choose to do an internal podalic version, which is to grasp the feet either with the hands or with a forcep and flip the fetus around in the uterus and deliver the fetus in the same manner I have just described.

Q. Doctor, based on your study of the D & X procedure, is it a necessary element that the fetus be converted to the breech position by instrumentation?

THE COURT: Do you mean necessary in definitional a definitional sense or—

MR. COPPOLINO: Yes, Your Honor.

BY MR. COPPOLINO:

Q. Did you understand my question, Doctor?

A. It depends on your definition, you know, whose definition you're using.

Q. I'm asking you for your understanding of a D & X procedure. Does your understanding include, as a necessary element, that the fetus has to be converted to a breech position, or to put it more clearly, if the fetus is already in a breech position, can the procedure, in your view, still be characterized as a D & X procedure?

A. Either case, it would be D & X, yeah.

Q. Doctor, I'm going to talk about labor induction in the next few questions. And just to give that context, could you describe what the labor induction method of pregnancy termination is in the second trimester?

[1675]

A. It's changed dramatically over the last 25 years, and the use of intraamniotic injections of hypertonic saline, Prostaglandin, urea have all but disappeared. Apparently they are still being used some places in the United States for reasons I'm not clear of in favor of Prostaglandin suppositories, and even that has evolved from Prostaglandin F2 Alpha and Prostaglandin E1 analogs. In Europe, Gemeprost is the most commonly-used agent. And in the United States, Misoprostol, Cytotec is. So that that the preparation is particularly well into the second trimester is going to be very analogous to D & E. Laminaria may be used, and followed by admission to the hospital, removal of the laminaria. Some folks would give antibiotics. Most would give an epidural for pain relief which would be like labor, epidural catheter in the back. And then Misoprostol suppositories would be used. And there's some discussion about what dose is optimal, but in general, they are used in the range of two to four hours. I might adjust that downward, in cases of fetal demise, to a little bit lower, with more advance gestational age. Even more recently, there are reports of the use of RU 486 instead of laminaria with far better results. And I think, always, a rule of thumb, I'm sort of making these numbers up a little bit, but they represent sort of the mid range of what's reported in the literature. That if you use 400, if you use * * *.

* * * * *

[1677] pregnancy—Let me rephrase that, Doctor. How do you evaluate whether a maternal health condition would lead you to terminate a pregnancy before its due date?

A. The usual context for me is when do you deliver the fetus. This is, in fact, what I get paid for basically. This is the art of high risk obstetrics. And it is a fairly complex and somewhat intuitive process of weighing the risk to the mother, in this case, of continuing the pregnancy, against the complications of prematurity. And, frankly, often since the fetus is often jeopardized by the mother's condition, often it's the fetus that is, in fact, the one in jeopardy and necessitates an earlier delivery. And so a point is reached at which we feel that that balance has slipped in favor of delivery for both patients, or certainly if either is in great danger, and delivery is effected.

Q. Okay. What are some of the specific factors, if you could describe them to the Court, which would indicate to you that the balance has slipped, as you put it, and it is necessary to deliver the fetus?

A. Well, in the case of the mother, for example, severe preeclampsia or toxemia pregnancy, which is a condition that manifests high blood pressure, proteinuria, and very often abnormalities in the liver, seizures, would become eclampsia, and more frightening, abnormalities of kidney function, kidney failure. And if this is very early in * * *.

* * * * *

[1681]

A. Because there is no circumstance where physically killing the fetus is required to somehow magically improve the mother's health. What is required is ter-

minating the pregnancy, and there are a variety of different ways to do that, but you know cesarean section is a procedure done over a million times a year in the United States. We have enormous experience with it. It is remarkably safe, and is a very reasonable approach to delivery, particularly near term. And we have also got extensive experience with induction of labor, and those are very safe and reasonable alternatives for terminating the pregnancy.

Q. So, Doctor, I think your answer to this question will be clear, but I want to state it for the record and have you answer it. In your opinion, is the D & X procedure ever medically necessary to preserve the health of a woman carrying the fetus past the point of viability, if measured at 23 and six/sevenths weeks?

A. By definition, any procedure that requires the intentional killing of the fetus isn't going to improve the mother's condition.

Q. Therefore, post-viability—

A. Correct.

Q. —D & X procedure simply isn't necessary?

A. Correct.

Q. Let's talk about pre-viability.

[1682]

THE COURT: Mr. Coppolino, I assume that—I don't mean to be tedious or obvious, but your question, as I understood it, was related to health.

MR. COPPOLINO: Yes, your Honor.

THE COURT: I would assume the answer would be the same with respect to life of the mother, but I'm not sure.

BY MR. COPPOLINO:

Q. Let me put that question to the doctor, Your Honor. Is there any condition or any circumstance in which it would be necessary to take a destructive act against the fetus, after viability, in order to preserve the life of the mother?

A. I doubt it. I mean, there may be an incredibly rare circumstance that I can't, you know, at this moment conceive of, but in which case, obviously, one should do whatever is necessary to preserve the life of the mother.

Q. Given the advances in health care that we have had over the past 20 or 30 years, have you ever seen a circumstance in which it has been necessary to take the life of a fetus after 23 and six/seventh weeks in order to save the life of the mother? Have you ever seen such a circumstance?

A. No.

Q. Again, let's talk a little bit about the pre-viability stage now. Are there circumstances relating to the physical health of the mother that may require the termination of the pregnancy prior to viability?

[1683]

A. Yes.

Q. And it's fair to say, Doctor, in these circumstances, death of the fetus will always occur?

A. By definition.

Q. And this is because the fetus cannot sustain life on its own prior to viability?

A. Correct.

Q. Are these circumstances common; that is, when it's necessary to terminate a pregnancy prior to viability, and the fetus, as a result, is not going to survive, are those common circumstances?

A. Yeah. Words are important to lawyers. I understand that they are somewhat important to obstetricians. Common is one of those words, and I would say that they are uncommon from the perspective of a population-based statistical analysis, but for high-risk obstetricians that see particularly these kinds of patients, they are not that uncommon. And so we are talking about conditions that might be on the order of one to five per thousand.

Q. Say that again, Doctor.

A. One to five per thousand.

Q. Per thousand?

A. Live births.

Q. Okay. Well, if you don't like my word common, what word would you use to describe the frequency of the termination * * *.

* * * * *

[1686] a break, we were in the midst of untangling an adjective to describe the frequency of pregnancy terminations, pre-viability, for maternal health condition. And I would just like you to take a shot at giving us a description of the frequency or rarity of pregnancy terminations from a maternal health condition prior to viability.

A. Direct object, noun, not adjective.

Q. A sentence would be nice.

A. So that the answer is that it would reflect the occurrence of a severe medical complication or obstetrical complication prior to viability essentially. And it would, so—for example, I'll give you some examples, because it will be hard for me to give you an absolute number. But about 3% of women develop preeclampsia. And of that a percent, a very small percent, less than 10%, will develop severe preeclampsia before 28 weeks. And so an even smaller percentage than that, maybe one in a thousand, will develop it before viability. Preterm deliveries are frequently associated with infection. That complicates 12.1% of all live births, but, in fact, the vast majority of those pre-term deliveries occur before 28 or after 28 weeks. So the occurrence of infection, premature labor and so forth, before 24 weeks, would be certainly less than 1%. And you can sort of go through this in a systematic way, and the answer is going to probably be that the occurrence of a [1687] life-threatening condition that would necessitate, or health threatening condition, that would necessitate termination of the pregnancy before viability, certainly less that 1% of all pregnancies. Probably on the order of one in a thousand or so, perhaps as high as five in a thousand of all pregnancies.

Q. Okay. Thank you, Doctor. I'm going to ask you, I'm going to ask you about some specific health conditions that a woman may face that may be an indication for terminating the pregnancy before viability. I want to ask you about some of the safe methods for doing that. But before we get to the specifics, I want to ask you this question. Do safe and effective ways exist to terminate a pregnancy for a maternal health reason prior to viability without the need to resort to the D & X procedure on a living fetus.

A. Yes.

Q. Would it ever be necessary, in order to protect the health interest of a woman who needs a pregnancy termination, prior to viability, to perform a D & X that takes a destructive act against a living fetus, in your view?

A. Can you rephrase that?

Q. Would it ever be necessary, in order to protect the health interests a woman who needs a pregnancy termination, prior to viability for a maternal health reason, to ever [1688] perform a D & X procedure?

A. Well, generally not. I mean, I think I made this clear that I really can't conceive of any specific condition that would specifically warrant a D & X, the expert's examples notwithstanding. And I would say that if there is such a condition, that I, at this moment, can't bring to my mind. There are methods of inducing feticide, of causing the fetus to no longer be living, that would then allow the procedure to be done.

Q. Okay, so you mentioned severe preeclampsia in your testimony here this morning. That might be an indication for terminating a pregnancy prior to viability?

A. Yes.

Q. Would the D & X procedure ever be necessary to safely terminate a pregnancy for a woman who needs a termination?

A. I don't believe so.

Q. I think some of the other examples we have seen in the declarations and testimony, Doctor. Renal

disease is one. What types of renal disease conditions have you seen in pregnant women that you've treated?

A. Many. The most common forms relate to the long-term effects of diabetes on the kidneys, and a condition called glomerulonephritis, another condition called chronic interstitial nephritis, and very often, kidney disease related to Lupus or other auto-immune diseases.

[1689]

Q. Doctor, might those diseases be an indication for termination of pregnancy prior to viability?

A. That is very rare.

Q. All right. And in those circumstances, in those very rare circumstances where it might be necessary to terminate a pregnancy prior to viability for a renal disease, would the D & X method ever be necessary to safely terminate that pregnancy for a woman who needs a termination?

A. I can't see a reason why it would be.

Q. Doctor, you mentioned placenta previa earlier today. I believe you mentioned you published an article on that. Could you just briefly describe what placenta previa is?

A. Placenta previa is a condition where the placenta rests over the entrance to the cervix.

Q. Is that a condition that might be an indication for a termination prior to viability?

A. Very rarely. Generally speaking, placenta previa has become symptomatic. They begin to bleed usually around 36 weeks, so it's usually a problem of very late pregnancy.

Q. Is the D & E procedure ever necessary to safely terminate a pregnancy for a woman who has placenta previa?

A. I think there are compelling arguments that surgical abortion, in which surgical abortion is preferable to medical abortion in that setting. I don't see that D & X versus D & E would matter.

[1690]

MR. COPPOLINO: Your Honor, may I approach the witness?

THE COURT: Sure.

BY MR. COPPOLINO:

Q. Your Honor, I have handed the witness what has been marked as Court Exhibit 3. Doctor, this is an exhibit which has been placed into evidence in this case, and it appears to be a letter to Senator Diane Feinstein from Dr. Phillip Darney at San Francisco General Hospital. I would like you to take a look at the summary in this letter of two cases described, and I'm going to ask you to comment about them. So just below the second full paragraph, there is a case summary which begins a 25-year-old. Do you see that?

A. I do.

Q. Would you just read that to yourself for a moment? Have you had a chance to read it, Doctor?

A. Yes.

Q. Perhaps so the record is clear, I might read it in, Your Honor.

THE COURT: Sure.

MR. COPPOLINO: In this case summary, in this letter, it says a 25-year-old with two previous vaginal deliveries and bleeding placenta previa and a clotting disorder at 20 weeks was referred for termination of pregnancy. After checking her coagulation parameters and [1691] making blood available for transfusion, we dilated the cervix overnight with laminaria and planned uterine evacuation when adequate dilation was achieved or bleeding became too heavy to replace. Within 12 hours, cervical dilation was three centimeters and heavy bleeding had begun. We removed the placenta quickly and used the quote, intact D & E, unquote, approach to compete the abortion and accomplish quick control of blood loss. The patient requires a transfusion of two units of whole blood and was discharged the next day in good health. Doctor, based on the information that I have just read that's in this letter, what is your view as to the use of the intact D & E procedure in this case?

THE WITNESS: Sort of like getting a phone consult. There is a lot of information I would like to have. Is the clotting disorder truly a clotting disorder where the woman is at risk for clotting in her blood; thrombosis, or as it seems to play out in this scenario, does she have actually a bleeding disorder, maybe a low platelet count, or some other—von Willebrand's disease. Some other condition that promotes bleeding. So, first of all, it's a little unclear if she has a bleeding condition that we should treat the bleeding condition before whatever termination is undertaken. And it shouldn't matter which of these three, medical D & E, or intact D & X, are performed. If it's [1692] really a clotting condition, and it may well be that, then I suspect what their concern was having the patient off anticoagulant therapy

for a longer time, if there were an induction of labor. And so they may well have placed the laminaria—whatever they did, while she was still anticoagulated, which is why she bled. And, then obviously, they wanted to move very quickly in doing the termination. In that context, ag[illegible] think the time to do a D & E and D & X, at leas[illegible]ccording to Chasen's study, was the same. And I would suggest if the law were in force, they could have injected KCL. They are very skilled at doing that at UCSF. They could have injected Lidocaine. They could have injected Digoxin, a variety of different ways to induce fetal death, then have done an intact D & X.

Q. I would like to turn to the second example on this document, Court Exhibit 3. I'll just read it for the record. A 38-year-old with three previous cesarean deliveries and evidence of placenta accreta was referred for pregnancy termination at 23 weeks, because of her risk of massive hemorrhage and hysterectomy at time of delivery was correctly estimated at about 75%. After—SFGH, which I believe stands for San Francisco General Hospital, after SFGH sonographic studies confirmed placenta previa and likely accreta, we undertook cervical dilation with laminaria and made blood available in case transfusion was [1693] required. To reduce the 75% probability of emergency hysterectomy in the situation of disseminated intravascular coagulation, (DIC) is quite likely with accreta. We decided to empty the uterus as quickly as possible with the intact D & E procedure and treat hemorrhage, if it occurred with uterine artery embolization, before our patient lost too much blood and hysterectomy was our only option. This approach succeeded and she was discharged in good health two days later. Doctor, what is your

evaluation of the use of D & E in the circumstances described in this paragraph?

A. I'm still a little in shock actually. The placenta accreta is where the placenta invades the wall of the uterus. I see many of these patients in New York. We have a very active service where we have referred these patients all over the city, in fact, the region. So I personally cared for a good number of these patients. The incidents of placenta accreta has risen dramatically, because of the higher C section rate. The management of these patients, they generally are not symptomatic to 36 weeks. I have no idea why they would want to do a termination at 22 weeks, unless the woman was interested in a termination. The management of placenta accreta is cesarean hysterectomy. Anyone that attempts to do anything short of that is playing an incredible game with this patient's life. Now, this may have been a patient that deeply wanted to retain her [1694] fertility. Well, in which case, why was she terminating a pregnancy? That makes no sense to me. It's very clear from the literature—it's very clear from our experience that the critical event, in the management of placenta accreta, is definitive surgery at the time. Conservative management has failed time and time again. It's placed the patient's life in great jeopardy. The only conceivable reason you might do it is in a woman whose *[sic]* never had children, desperately desires children. If the accreta were small, I have no idea why anyone would try to do this, to be honest with you. So should they have done this? No. Did they get incredibly lucky? Yes. If there had been a bad event, would they have been sued by many, many lawyers? Yes, absolutely.

Q. Now, Doctor, in those cases where a surgical abortion may be a better choice for termination, would the D & E, by dismemberment, be a safe and effective method of abortion?

A. Well, in somebody that had multiple C sections and so forth, it would be a reasonable alternative.

Q. Okay. Couple more specific conditions I just want to address with you, Doctor. What is HELLP Syndrome, H-E-L-L-P?

A. It's a variation of preeclampsia or toxemia which HELLP stands for hemolysis, breakdown of red blood cells, low platelet count, elevated liver function test, putting it in [1695] that order. It's very serious. You have liver failure. You can have hemorrhage, seizures, and it's frequently associated with small fetuses and so forth. So diagnosis of that before 24 weeks would certainly be an indication for medical termination or termination of the pregnancy.

Q. When does that condition typically present?

A. It usually presents around 30 to 34 weeks.

Q. Is that a condition that might be an indication for termination of pregnancy pre-viability?

A. Yes.

Q. Now, in that circumstance, Doctor, is the D & X procedure ever necessary to safely terminate a pregnancy for this condition pre-viability?

A. She has a low platelet count, so a better approach would be a medical termination. I don't want to incur the risk of uterine perforation, cervical lacerations, etc.

Q. All right. Doctor, next condition I would like you to discuss has been referred to as sepsis. What is sepsis?

A. It's a very bad infection.

Q. Of the—

A. Sepsis is a general term, so it could be of the brain or the heart, or of any part of the body.

Q. In the context of pregnancy, is the condition typically associated with the uterus?

A. Yes.

[1696]

Q. All right. Is there a point in time when that condition, sepsis of the uterus, typically presents or could it occur at any point in gestation?

A. At any point.

Q. All right. Might that condition be an indication for termination of pregnancy pre-viability then?

A. Well, yeah. I misspoke. It's much more common near term. It's much more common in conjunction with pre-term rupture of the membranes or premature labor, which generally as I have already explained, occurs after 34 weeks. But clearly an infected uterus what we call chorioamnionitis, or intraamniotic infection, before viability is an absolute indication for terminating the pregnancy.

Q. And so for sepsis of the uterus, or chorioamnionitis, as you refer to it, is the D & X procedure necessary to safely terminate a pregnancy for a woman who has that condition?

A. Generally speaking, these are women in labor, active labor. Infection triggers labor. The cervix is already dilated. So you could continue the medical termination. The fetus is usually dead by that time, or you could do a D & E for sure. I don't see the relative advantages or disadvantages of the D & X, except that in an infected uterus, the wall may be damaged. The wall of the uterus may be damaged and thinned, and there may be a theoretical advantage to minimal numbers of passes in that condition. [1697] And so that might be an advantage to a D & X, but there is no data to drive that.

Q. Let's talk about a couple of heart conditions. What is peripartum cardiomyopathy?

A. Peripartum cardiomyopathy is a condition which can have explanations like high blood pressure, but most commonly is unexplained. Usually presents in the third trimester but it can occur in the second trimester and it is associated—the cause is unknown. The patients in the past had a 50% mortality rate. There is a 50% recurrence rate in subsequent pregnancy.

Q. Does that condition generally occur near term?

A. Generally speaking, but not always.

Q. It might be an indication for pregnancy termination pre-viability?

A. It could be.

Q. Is a D & X procedure ever necessary to safely terminate a pregnancy for that reason?

A. Again, all three are perfectly acceptable. The key is to optimize the mother's cardiac condition before you do the procedure.

Q. If the mother has a serious cardiovascular condition, would you advise her to wait if possible until after 20 to 23 weeks gestation to terminate?

A. Well, it depends on the cardio. I might advise her not [1698] to get pregnant. Depends what that cardiac condition is. Some are serious but are consistent with being able to deliver at term or near term. Some, pulmonary hypertension, for example, where there is high blood pressure in the lung, I would recommend terminating a pregnancy.

Q. And in that circumstance, would the D & X procedure ever be necessary to safely terminate the pregnancy prior to viability?

A. Well, again, I think that all three would be reasonable. There may be certain specific conditions that might push you to one or the other procedure.

Q. All right. Doctor. What about—Let's do one last. What about leukemia. What is leukemia?

A. Leukemia is a disorder of the white blood cells in which they reproduce in an uncontrolled fashion, and usually there is anemia and low platelet counts associated with that.

Q. And would that condition ever be an indication for terminating pregnancy prior to viability?

A. Yes, because the key—Most therapeutic agents to treat the mother would be toxic for the fetus.

Q. Would medical induction be a safe method of abortion for that termination, if necessary?

A. Particularly if there were low platelet count.

Q. Would it be preferable over a surgical termination of abortion?

[1699]

A. If there were a low platelet count.

Q. Doctor, another condition we have seen reference to is called proliferative retinopathy. What is that?

A. It's a disorder of the small blood vessels in the retina associated with diabetes. Usually occurs in patients with poor diabetic control, poor control of their glucose, and usually occurs after about 15 years of having the disease. It tends to get worse in pregnancy, and requires meticulous ophthalmological surveillance and is treated with laser therapy. We have published on this with *Laser Therapy*. It should not affect the natural history of the condition and certainly not an indication for termination of pregnancy.

Q. How often do you see patients in high risk obstetrics that have this condition?

A. Rare. I think if you have a busy service with a large number of diabetics, that you'll see it in maybe four or 5% of your insulin-dependent, pre-gestational diabetic patients.

Q. In your view, Doctor, for a woman who is facing this condition that has a need to terminate a pregnancy pre-viability, are there methods of safe termination other than the D & X procedure?

A. Well, again, I don't really view it as an indication for termination. I view it as an indication for laser therapy of the retina. But if the patient wishes to terminate, and [1700] if there may be other exigencies that require that, then, again, any of those three methods are reasonable.

Q. And, Doctor, when you say any of three methods of abortion may be reasonable, you're referring to D & E, D & X, and medical induction?

A. That's correct.

Q. Is there any evidence in the medical literature that you're aware of, that the D & X offers any safety advantage over D & E or medical induction?

A. No.

Q. I would like to ask you for a few minutes about fetal anomalies. In your medical opinion, are there safe methods of pregnancy terminations in cases where there are fetal anomalies?

A. Yes.

Q. Is it ever necessary to use the D & X procedure to terminate a pregnancy with a fetal anomaly?

A. Not to my knowledge.

Q. We have seen reference to a condition called hydrocephaly. Would you tell the Court what hydrocephaly is and if a pregnancy termination was elected in that circumstance, are there safe and effective methods to terminate that pregnancy, other than utilizing the D & X procedure?

A. It's a condition in which there is extra fluid in the [1701] brain, and that cerebral spinal fluid causes expansion of the cavities in the brain. The head, occasionally, can be enlarged. Certainly the ventricles in the baby's brain are enlarged, and it can be terminated by any of the three means. I would suggest and recommend that they aspirate the fluid in the brain before they do any of the procedures to ensure that the fetus is delivered without any complications.

Q. And if that procedure is utilized—What is that procedure called by the way?

A. Cephalocentesis.

Q. If a cephalocentesis is utilized to reduce the size of the skull, are there safe and effective methods of terminating that pregnancy without the need for resorting to the D & X procedure?

A. Again, all three would be acceptable.

Q. But the D & X procedure is one for which any medical evidence is lacking to show it's particular safety; is that correct?

A. Correct.

Q. Doctor, you have mentioned this morning, you used the term feticide. And I just wanted to ask you some questions about that. If there were a circumstances where the need were to arise that the D & X procedure might be considered necessary to end a pregnancy, or in the physician's [1702] judgment, a potentially useful procedure, is it necessary to utilize that procedure on a living fetus in your view?

A. Well, again, if one wants to do an intact D & X, the law is in force, then you would have to do that.

Q. Let me just maybe ask the question a little differently. Are there safe and effective ways to induce fetal demise in order to avoid doing the D & X on a living fetus?

A. Well, you would still do the D & X. I understand. Yes.

Q. What are those methods?

A. You can inject potassium chloride into the heart. You can inject Digoxin into the heart, and you can

inject Lidocaine into the heart. And there are some additional methods as well.

Q. Is potassium chloride sometimes referred to as KCL?

A. Yes, it is.

Q. Does the injection of KCL, is that routinely used in obstetrics?

A. It's used in a variety of different settings, yes.

Q. What are among the settings at which it's used?

A. A condition or a procedure called multifetal reduction where there is maybe four or five or six fetuses, and the person performing the procedure will inject potassium chloride into three or four of the embryos to reduce the number to two or three.

Q. How is the injection of Digoxin performed, Doctor?

[1703]

A. Same way. Under ultrasonic guidance.

Q. And where typically—Can the Digoxin be injected directly into the fetus or the amniotic sack?

A. It can be injected into the umbilical cord, into the heart, into the fetus itself, the muscle or body cavity of the fetus, or into the amniotic fluid.

Q. Does the injection of Digoxin require a particular skill?

A. In the reverse order I just gave you, it would require some significant skill to inject into the umbilical cord, less into the heart, still less into the body of the fetus, and very little into the amniotic fluid.

Q. How does the technical difficulty of injecting KCL compare to the performance of the dilation and extraction procedure itself?

A. Well, it would really depend on the interval between the injection and the procedure. The longer the interval of fetal death, the more the tissue would become macerated and softer, and more compliant, and presumably the less risky the procedure would be for a D & E. But if it's done too quickly to the procedure, it would have less of an effect.

Q. Doctor, do you know if such injections are used at Yale University?

A. Yes.

Q. Both KCL and Digoxin?

[1704]

A. Just KCL.

Q. Just KCL. When are such injections are given?

A. They are given for multifetal reductions and at the time of terminations further advanced in gestation.

Q. How would you characterize the risk of an injection of potassium chloride?

A. To who?

Q. To the mother.

A. Presumably negligible.

Q. Now, I would like to turn and focus a little bit more generally on safety risks of abortion procedures generally, and focusing on the 20- to 24-week gestational range. You have testified, I believe, that the available options at that gestational range would be D & E, medical induction, and D & X; is that correct?

A. And hysterotomy.

Q. And hysterectomy. Doctor, in your opinion has the medical induction method of abortion between 20 and 24 weeks gestational age been established as a safe method of abortion?

A. It has.

Q. Has it been safely established in the scientific and medical literature?

A. It has.

Q. In your opinion, Doctor, has the D & E by dismemberment [1705] method of abortion, at 20 to 24 weeks gestational age, been established as a safe method of abortion?

A. It has.

Q. Has its safety been established in the scientific and medical literature?

A It has.

Q. In your opinion, Doctor, has the dilation and extraction, D & X method of abortion, between 20 to 24 weeks gestational age, been established as a safe method of abortion in the medical and scientific literature?

A. Until Steve Chasen's report, there really hasn't been significant literature on the topic. So his report suggests it's safe.

MS. SMITH: Your Honor, I'm sorry to interrupt Dr. Lockwood, but I was told that this witness would not be testifying about the Chasen article.

THE COURT: Well, the witness's answer, which you may not have heard, was certainly something about

it being safe. I mean—So I appreciate that, but are you moving to strike the answer because he was not disclosed to talk about the Chasen article?

MR. COPPOLINO: Excuse me. Your Honor, it's not my understanding that we said that. In fact, he was deposed for several hours on this article at his deposition in which Ms. Smith was present.

[1706]

THE COURT: I don't know. We'll sort this out. I just want to know what the nature of the objection is, and given what the answer was, do you object?

MS. SMITH: I'll withdraw my objection, Your Honor.

THE COURT: All right. Well, the objection is withdrawn. Pardon us. Go ahead.

BY MR. COPPOLINO:

Q. Thank you. Before we get to the specifics of the Chasen article, I want to ask you a few more questions. What's your response to the argument the D & X procedure is intuitively D & E, because there are fewer instrument passes into the woman's uterus? Is that sufficient in your view to establish the safety of the dilation and extraction procedure, at 20 to 24 weeks, such intuitive or anecdotal evidence?

A. One would not use intuitive or anecdotal evidence to firmly establish procedure as an acceptable and preferred alternative clearly. On the other hand, I believe that it does permit it to be used in—preferably in the setting of studies where its safety is going to be validated, and I think there is compelling enough arguments as to its safety, that I certainly would not want to prohibit its use in my institution.

Q. But in your opinion, Doctor, what would be required to establish the safety of the D & X method of abortion?

[1707]

A. I certainly would like to see, to start with, retrospective studies of those centers that have large experience, preferable comparing it to D & Es and doing multiple logistic progression to control for variables such as parity, cervical dilation, gestational age. And get some sense as to whether or not there is a lower incidence of—lower incidence of hemorrhage, perforation, the occurrence of lower hematocrits, decreased procedure time. The various end points that theoretically appeal to those who do it.

Q. Doctor, do you think the D & X procedure could be subject to a randomized trial in order to study potential complications in the procedure?

A. And I believe that it could be done.

Q. And how?

A. I think that patients would have to be fully informed that they were going to be part of a study. I think that strict guidelines that led to differing degrees of cervical dilation would have to be employed, and that patients would have to be randomized at the intent to treat point. So that even if the procedure turned out to be—was going to be intact D & X, it turned out to be a D & E, they are part of the intact D & X group and vice-versa. And having done all that, then appropriate comparisons could be made of blood loss, procedure time, complication rate and so forth.

[1708]

Q. Now, short of a randomized trial like that, would other methods be available to study the D & X?

A. You just mentioned that retrospective chart reviews would be very helpful.

Q. Doctor, how reliable would you regard a case review, solely by the physicians who have utilized the procedure as a means of conclusively determining the safety of the procedure?

A. Well, I won't dismiss descriptive studies as being without some value, but, in general, we use them as the basis for then pursuing additional studies; whether they are retrospective—what we call cohort studies or case-controlled studies, or actual randomized clinical trial.

Q. General question on risks of abortion, Doctor. Do the risks of abortion procedures bear any relationship to gestational age?

A. Oh, absolutely.

Q. In what way?

A. Well, for example, for each week of gestation beyond eight weeks, there is a 38% risk of increased risk of mortality, so clearly gestational age has a dramatic effect on risk of mortality.

Q. Doctor, what are some of the risks of the medical induction procedure between 20 and 24 weeks?

A. The primary risks are retained placentas, infection and * * *.

* * * * *

[1712]

Q. All right. I would like to ask you about the potential risks of the dilation and extraction, D & X method of abortion. Doctor, have the risks that have been associated with the D & X method of abortion been established in the medical and scientific literature?

A. There is no literature at this point. The Chasen article will be a point of information.

Q. Now, you believe—Do you believe the risks of D & E and D & X could be comparable?

A. I do.

Q. Do you see any evidence that the D & X procedure is a safer procedure?

A. Beyond the intuitive or theoretical advantages, no.

Q. Now, some circumstances, you previously testified that the D & X might be reasonable in some circumstances; is that correct?

A. Correct.

Q. Could you ever envision a circumstance in which the D & X procedure would be required as opposed to a D & E or a medical induction?

A. No.

Q. What do you see, Doctor, as the potential risks of the D & X procedure, both long- and short-term?

A. Well, short-term, they would be identical to those of a D & E. I think the theoretical benefit of an intact D & X [1713] is fewer manipulations, which might reduce the risks of perforation. Risk of perforation is

not insubstantial. Can be as high in some studies as 1.4%; in others as low as .2% but it's the most feared complication. So that, I think, is the great appeal of the procedure. So that's, at least, a theoretical advantage. The second part of your question was?

Q. I asked you what you saw as the potential of short and long term?

A. That's really the short-term advantage. Obviously the long-term disadvantage, and many people have spoken on this, is the issue of would further cervical dilation increase the risk of prematurity.

Q. And is that risk, Doctor, of prematurity, in your view, the primary long-term concern with the D & X procedure?

A. I may be very biased on this topic, but, yes. I would view it as the most serious.

Q. Is there any evidence that you're currently aware of that discusses the relationship between abortion and subsequent pre-term birth?

A. Yes, there is.

Q. What does it show?

A. Well, there are conflicting reports, and the largest reports we talked about briefly at my deposition are from Europe, both from France and Denmark. The French study [1714] suggested that abortion, induced abortion, and fairly ill defined, I'll admit, was associated with approximately a 1.3 fold increased of prematurity. And if there were two abortions, at one point I believe it was a 9-fold increased risk of prematurity. That study had several advantages. One it was a snapshot of the French population derived from their public health records in 1995. So modern abortion techniques would

have been employed. And it was obviously a very comprehensive database. That, I would say, is concerning to me. And that report in the *British Journal of OB/GYN* in 2001, sort of lingering in the back of my mind, is a concern. However, it is very unclear that the type of abortion that we are talking about here was the type of abortion applied in that study. The second study was a study from Denmark involving 15,000 patients who were followed up, and they found an association between prematurity and previous induced abortion of 1.9 if you had one, and a 2.6-fold increased risk if you had more than one. But, again, the disadvantage of that study, from my perspective, is that it was—it was a recent publication from 1999, in *Obstetrics and Gynecology*, the data was accumulated in the 80s. So we are not sure that the same techniques were used. Now, the most—the vast majority, 90% of those patients had D & Es, but the D & Es ranged, I believe, from nine to, let's say, 14 weeks. They were [1715] mostly done in the first trimester. Again, we don't know what the risk would be. Some have argued that the further along you go, the greater the risk because the laminaria are not the most physiologic way to dilate the cervix. Others have argued that earlier D & Es might even be more dangerous, because you're mechanically dilating the cervix. I think, since this is, in fact in the focus of my professional existence, it's a topic I'm very, very interested in. And I am concerned, in general, about the association of abortions and prematurity. And I don't know the answer, to be honest with you. But I'm certainly suspicious and would certainly like more data.

Q. I would like to show you—May I approach the witness, Your Honor?

THE COURT: Sure.

BY MR. COPPOLINO:

Q. Doctor, I have handed you what's been marked as Plaintiff's Exhibit 27. Do you recognize this exhibit, Doctor, as a study done by Dr. Chasen and several others?

A. I do.

Q. Have you had occasion to review this study?

A. I have.

THE COURT: All right, let's stop here for just a minute. There was previously apparently a brewing dispute that I hope we can take care of. Do you have an objection * * *.

* * * * *

[1719] word.

MS. SMITH: Your Honor, if Your Honor is not tired of hearing about the study, then I think we should go ahead, but I would ask that I be permitted to renew my objection if there is some opinion that was not disclosed during the deposition that is some new criticism that he's come up with, then, that hasn't been disclosed, and that then I might renew my objection.

THE COURT: Yes. That will be permitted, and the objection as to the cumulative nature I will construe to have been withdrawn. Go ahead, counsel.

BY MR. COPPOLINO:

Q. All right. Dr. Lockwood, you have reviewed Dr. Chasen's study; is that correct?

A. I have.

Q. Do you have a view as to whether this study is adequate to demonstrate that the D & X procedure has

safety advantages over the procedure of D & E by dismemberment?

A. No.

Q. And why not?

A. Well, the study essentially shows that they are remarkably similar in their outcomes. The procedure times were literally identical, and the blood loss was literally identical, and the occurrence of complications was virtually identical. I would say that to be fair to—if one can be [1720] fair to a procedure, to be fair to the intact D & X procedure, the D & X was generally done at a more advance gestational age, which I have already testified, increases the risk of surgical abortions for sure at higher parity. That may have actually made it easier potentially, but might have increased the risk of perforation. And so, you know, and the cervix was obviously more dilated. I don't think that affects complications. So from that standpoint, then, I think that one can conclude that it would be extraordinarily unlikely that these two procedures have markedly different occurrences in the rate of complications, short-term complications.

Q. Doctor, do the size of the patient groups in this study, do you think that they are sufficient to draw meaningful conclusions regarding the safety of the two procedures without further studies?

A. Well, they are not trivial; 120 patients and 263 patients are certainly a very large study. One that would—I think, prove to be a valid indicator of certain—this gets into some really complicated statistical stuff, but basically, there is something called power analysis to prove the absence of a finding is real. And for some procedures where we, you know, where we

might be looking for a 50% increase or decrease in a complication or a procedure time or blood loss, you can be pretty comfortable that there is [1721] not anything of that magnitude going on here. Could there be a 5% difference, or a 10% difference in bleeding, blood loss or procedure time, yes. That's not terribly important clinically. The study is obviously underpowered, doesn't have adequate numbers to rule out differences in grave complications; death, perforation, which would require many, many more patients than this. But it gives us a good sense that the overall rate of standard complications, immediate short-term complications were very similar in the two groups.

Q. What does it tell us with respect to potentially significant complications?

A. Not much.

Q. We were taking a moment ago about pre-term birth. Do you know what the disparity in this study is with respect to the long-term complication of pre-term birth that is reported in comparing two procedures?

A. The reported difference was 11.8 versus 4.4%.

Q. 11.8 percent?

A. For the D & X group, and 4.4 percent for the D & E group.

Q. What's your assessment of that disparity?

A. It's not statistically significant, so I wouldn't draw an enormous amount of, you know—put an enormous amount of weight on it. And as mentioned in the paper, there were [1722] additional risk factors in the D & X group for subsequent premature delivery. So I think, you know, formally as a clinician-researcher, I wouldn't draw any conclusions from it. Would this pro-

voke me to want to do additional studies? Absolutely. does it sort of already fit into my bias about the procedure as an expert on prematurity? Yes, it does. Would it make me prohibit its use in—No, but it certainly would prompt me to want additional studies.

Q. That's with respect to the potential pre-term birth complications?

A. Correct.

Q. Doctor, in your opinion, does the skill of a physician play any role in considering the risk of a procedure?

A. Clearly.

Q. Why is that?

A. In general, there is very good evidence in the medical literature that the more often a procedure is done by a doctor at a facility, the lower the complication rates. And there is specific data in the literature to reflect that in a setting of surgical abortion as well.

Q. And I want to ask you about that next, the setting of the abortion. In your opinion, does the setting in which an abortion take place play any role in assessing the risk of the procedure?

A. Absolutely.

[1723]

Q. Why is that?

A. Well, for example, the more senior, the more experienced a given practitioner would be, the less likely the complication rate. Residents have a higher complication rate than more senior people. If it's performed in a hospital with access to critical care specialists, rapid transfusions, superb anesthesia, one

would assume that would be a safer environment, given the same advanced gestational age, than a clinic that doesn't have access to that kind of technology and so forth. So I think that the physical setting, and the clinical setting, and the skill of the practitioner would impact the success of the procedure.

MR. COPPOLINO: Your Honor, may I approach the witness?

THE COURT: Sure.

BY MR. COPPOLINO:

Q. All right. Doctor, I handed you what's been marked as Defendant's Exhibit 501, which is a copy of a *Partial-birth Abortion Ban Act of 2003*. Have you seen this before, Doctor?

A. I have.

Q. I would like to call your attention specifically to paragraph 14A, which is on page S3-4. Have you read this paragraph before, Doctor?

A. I have.

[1724]

Q. And this paragraph discusses one of the findings of Congress with respect to the risks imposed by the partial-birth abortion procedure.

A. Correct.

Q. Do you agree with everything that is stated in this paragraph as to the potential risks of the partial-birth abortion?

A. No.

Q. Do you agree with some of them?

A. Not really. Very little.

Q. That's what I wanted to go through with you. I wanted to have you look at the risks that Congress stated here, and give us your views on whether you felt that those risks were overstated. Specifically, Doctor, what I would like to know is, with risks, such as amniotic fluid embolism, do you feel that the risk of amniotic fluid embolism is rare to begin with?

A. Yes.

Q. What is the rarity of that occurrence?

A. About one in 5,000 deliveries.

Q. And just so the record is clear, what is amniotic fluid embolism?

A. Well, it's been mentioned in the deposition. It's sort of a moving target, but the theory is that amniotic fluid enters the blood stream of the mother, and it causes [1725] cardiovascular collapse, and it causes a breathing abnormality. Traditionally, it has been thought to have an 80% mortality rate. It's probably closer to 40%, and we have—I published on this, and others have published on it. We all have our pet theories as to why it happens.

Q. All right. Doctor, is the risk of amniotic fluid embolism with medical—how would you compare the risk of amniotic fluid embolism using medical induction to that using a surgical abortion?

A. The theory is there is access to a maternal blood vessel, what we call venous sinusoid, in the uterus that would allow the amniotic fluid to enter into the cavity. And that would be associated with a contraction or sudden increase in pressure of the fluid. So you would be a little concerned that surgical procedures, D & Es, D & Xs, might uncover those blood vessels in a more

frequent setting than would a medical abortion. In fact, Steve's paper makes reference to a D & E with an amniotic fluid embolism. I don't think it's a common complication of abortions in general, but I would be a little more suspicious about surgical procedures than I would be about nonsurgical procedures. To be honest, I would be a little more suspicious about D & Es where there might be an increased risk of trauma than intact D & Xs where there might be a slightly reduced risk.

[1726]

Q. Directing your attention to that aspect of the finding which talks about conversion of a fetus to a footling breech. In your opinion, would conversion of the fetus to a footling breech create a potential risk to the mother?

A. It's possible that there could be trauma to the uterus as one is attempting that procedure.

Q. Is that a potentially serious risk?

A. Well, if you perforate the uterus, it would be, yes.

Q. So, Doctor, is it fair to say that you think there are some risks, some potential risks, to the D & X procedure?

A. I think there is some risk to all medical and surgical abortions.

Q. Is your concern with the D & X procedure primarily with concern to the longer term complications with respect to pre-term birth?

A. Absolutely.

Q. Doctor, in your opinion, is the dilation and extraction method necessary for purposes of diagnostic pathology?

A. Well, no.

Q. And why is that?

A. Well, it depends on what you're trying to—what the diagnosis that you're interested in would be. If it were a D and A diagnosis, or chromosomal analysis, a piece of placenta or amniotic fluid sample would be sufficient to give you that. If it were an anatomic analysis of the fetal [1727] brain, a medical abortion would be the appropriate way to do that. In general, with good ultrasound and with, even with D & Es, where there is a less trauma to the area in question, that can be a satisfactory method. There might be some circumstances where a D & X would allow better diagnostic information. For example, of maybe the thorax or the extremities, which might be damaged by the D & E procedure. But, in point of fact, there are very rare circumstances in which I will tell a patient she should have a medical abortion rather and a D & E to terminate an anomalous fetus. Of course, I give her full counseling. She has many options including continuing the pregnancy, but, you know, because the information to be gained is so marginally important for my purposes.

Q. In circumstances where you felt that a fully-intact fetus was necessary for any pathological diagnostic purpose, would a medical induction be a safe and effective means of pregnancy termination in order to obtain an intact fetus?

A. Barring any contraindications to it.

Q. Doctor, in a situation where it was necessary to obtain a diagnosis of the central nervous system, would the medical induction abortion be the preferable way?

A. Yes.

Q. Let me finish the question. Would be the preferable way to obtain the intact fetus?

[1728]

A. Yes.

Q. Would the use of Digoxin or KCL to ensure fetal demise at the outset of the procedure, in any way, negatively impact the physician's ability to make a pathological assessment?

A. No, as long as the interval between the injection and delivery were not too long.

Q. Doctor, you were asked at your deposition whether you believed, in light of declarations submitted by the plaintiffs, the ACOG policy statement, whether there was, quote, a significant body of medical opinion that in some circumstances for some women, an intact D and X may be a safer method of abortion than another option. Do you recall being asked that question?

A. I do.

Q. And do you recall agreeing with that statement?

A. I do.

Q. All right. What did you understand you were being asked in that question; what did you mean by your answer?

A. I would say that the context of the deposition, being surrounded by expert reports and so forth, that I

was talking about the expert opinion of the—essentially of the plaintiffs.

Q. Were you, in your answer, referring to the medical community at large, that the medical community at large [1729] constituted substantial medical authority for the safety of this procedure?

A. Well, the vast majority, 99% of OB/GYNs, don't do that procedure, and I would venture to guess that 99% of that 99% have no opinion one way or the other as to its usefulness and so forth. I think that those that are interested in this topic are those that do the procedure, and those are primarily high-risk obstetricians that are concerned about the long-term consequences, and, obviously, pro-life obstetricians that don't approve of any procedure.

Q. One more thing to talk about this morning. Doctor. Have you ever written anything about the Partial-Birth Abortion Act of 2003?

A. I'm holding it.

Q. And you're holding what's been marked as Plaintiff's Exhibit 60; is that correct?

A. That's correct.

Q. And what is this document?

A. This was a draft of an editorial in Contemporary Obstetrics and Gynecology.

Q. And you wrote this?

A. I did.

Q. When did you write this?

A. I think we asked that at the deposition. I wish I could remember the answer that I gave then. Maybe December 19th, [1730] 2003, or thereabouts.

Q. Doctor, at the time you wrote this draft editorial, had you reviewed any materials related to the Act?

A. From who?

Q. From the plaintiffs.

A. No.

Q. You don't recall reviewing plaintiff affidavits prior to writing this?

A. I do not recall that, no.

Q. Well, what were your views at the time that you wrote this editorial?

A. Well, pretty clear.

Q. Summarize your views as stated in this draft editorial.

A. I would crudely summarize these views. My feeling about this Act was that certainly it was within the Congress's purview to be able to ban any abortion procedure after viability. And in many ways, this editorial—I'm a little embarrassed to mention this, is a legal argument rather than a medical one. So with that caveat, my reasoning was something along the following, that the original Roe v. Wade decision, again, balanced reproductive options and reproductive choice, and autonomy with obligations of society to protect, as they described it, the potentiality of life. And in the third trimester, which they viewed as viable, I would say it's earlier. They argued that—that [1731] abortions, in fact, could be banned to protect the potentiality of life except in cases where the mother's health or life

were in danger. That in the first trimester, there should be no restrictions, and in the second trimester, to really briefly characterize this, the state had an obligation to protect the mother from potential harm from abortion. And that from that perspective, then, not only the partial-birth abortion, in my mind's eye, but any abortion procedure, could be banned after what I would view as viable, 23 and six/sevenths weeks gestation because there was no condition where the death of the fetus was required to preserve the health or life of the mother. However, I also opined in this editorial that the state would have to prove that partial-birth abortion, as they defined it was, in fact, more dangerous than currently available techniques, in order to ban it in the second trimester. And thirdly, that I had expressed concerns about the vagueness of the Act, such that it might be misconstrued by over-zealous prosecutors to outlaw all D & Es, and, thus, to create a real undue burden on access. I would say that as an obstetrician-gynecologist, and as a doctor, I don't particularly like—appreciate laws that restrict medical practice. I understand abortion is different. I understand this to patients. I understand this is probably an exception to that rule, although I still hold it as a [1732] general principle. And, finally, as an obstetrician-gynecologist, I'm enraged that our lawmakers would attach civil penalties to a field that is essentially being killed by the lack of tort reform. We have had 35% reduction in medical student applicants to our field. We have had 70 programs unfilled this year for our match. If you want your daughters and your granddaughters, not to get on the soap box here, to be able to have good smart obstetricians and gynecologists taking care of them, we have got to address that issue. And, clearly,

this exacerbated that, didn't help. I think that's a real brief summary of my views when I wrote it.

Q. So, Doctor, it's fair to say, you're not an advocate of the Partial-birth Abortion Act; would that be correct?

A. That would be correct.

Q. Nonetheless, testifying here today, you do believe there is no established scientific evidence demonstrating the D & X procedure is a safer procedure abortion; is that correct?

A. Correct.

Q. And you also believe that the D & X procedure requires further study in order to determine whether it has long term complications; is that correct?

A. Correct.

Q. So since the time you wrote your article, have your views evolved somewhat as you have gotten involved in this [1733] case?

A. They have in several respects. One is that I have focused to push, touch a sore point, on pain, so-to-speak. No pun intended. Because I view, again, the balance between reproductive autonomy and protecting the dignity and the life of the fetus, such that we should address pain between 20 and 24 weeks. I think I would feel strongly that it would be within the purview of the state, again, making a legal statement, that pain relief ought to be provided at the time of abortions. And if there is a more humane way to do it that's equally safe, that ought to be the preferred method of doing it, however one would define that. I would say though that the other area that I'm certainly, I think, more understanding of everyone's position on is the issue of

vagueness, which I think is at the heart of this entire Act. And I have come to the conclusion that, in fact, the issue of vagueness is really a legal issue, one to be decided by the courts and that, obviously, I have already stated, that if the law were interpreted in a way that reduced access, reduced the access of women to D & E, particularly at 14 weeks or 15 weeks or 16 weeks, that would be a real shame, and I think a violation of the spirit and, in fact, of the wording of the Roe v. Wade decision. If, on the other hand, the Courts interpreted this in a very strict way, perhaps with gestational age restraints, that I would see no [1734] objections to it, since it met my ethical arguments between 20 and 24 weeks of minimizing pain.

Q. And aside from your views on the potential vagueness of the statute, you testified this morning that there are safe and effective alternative methods for caring for maternal complications other than the D & X procedure; is that correct?

A. That's correct.

Q. You also testified, I believe, that where it may be necessary in some physician's judgment to use this procedure, an injection to reduce fetal demise can be safely administered prior to that procedure; is that correct?

A. Correct.

MS. SMITH: Objection, Your Honor. He's leading the witness and I believe mischaracterizing the testimony.

THE COURT: That will be overruled.

BY MR. COPPOLINO:

Q. And your answer?

A. Correct.

MR. COPPOLINO: Thank you, Your Honor.

THE COURT: Yes. Ms. Smith, would you want to start now, or do you want to come back and start fresh? Tell me what you would like. This clock says 12:45 or 11:45.

MS. SMITH: Why don't we take a break, Your Honor, * * *.

* * * * *

[1736]

MR. COPPOLINO: No. I don't know what it was. It just went away.

THE COURT: Fine. Thank you. Go ahead.

[Dr. Charles Lockwood—Cross]

BY MS. SMITH:

Q. Thank you, Your Honor. Good morning, Doctor. We met in New Haven at your deposition.

A. Good afternoon.

Q. Good afternoon. You're right. Doctor, you testified that high-risk obstetrics is somewhat of an art; didn't you?

A. I did.

Q. And that your decisions about when and whether an early termination needs to occur are somewhat intuitive; is that right?

A. True.

Q. And isn't it true also that performing surgical abortions in the second trimester is also something of an art?

A. True.

Q. And that decisions are also sometimes made by these surgeons based on their intuition?

A. True.

Q. Doctor, you would agree that Dr. Carolyn Westhoff and Dr. Steven Chasen are well-respected obstetricians and gynecologists and well respected in the field?

[1737]

A. Yes.

Q. And that they have considerable expertise in the field of induced abortion; is that right?

A. Yes.

Q. Doctor, was it your testimony that you believe that all post-viability abortions should be banned; is that right?

A. I don't have a political position on this. I said that I didn't believe that there were any indications where it was required to kill a fetus to preserve the life for the mother after viability.

Q. Or the health?

A. Or the health.

Q. Okay. Thank you for that clarification. And when you say viability, just so we are using the same terminology, you believe that viability occurs after 23 completed weeks, by which you mean 23.67 weeks LMP?

A. That's correct.

Q. And your concerns about abortions after 23 completed weeks extend not only to the intact D & E procedure but to all forms of pregnancy termination?

A. That's right.

Q. And also just to clarify a point from this morning, you have never actually performed an induction abortion; is that right, Doctor?

A. On a living fetus.

[1738]

Q. On a living fetus, right, and you have never actually performed an intact D&E?

A. On a living fetus.

Q. On a living fetus. Okay. And you've never observed another physician performing an intact D & E on a living fetus?

A. Correct.

Q. Is that right? Okay. Doctor, do you still have Plaintiffs' Exhibit 60 in front of you?

A. I do.

Q. And this is the draft you prepared for the Journal of Contemporary OB/GYN; is that right?

A. That's right.

Q. And I think you testified you drafted this sometime in December?

A. Correct.

Q. You then sent the draft to Sheila Gowan who is an Assistant U. S. Attorney in the Southern District of New York and who represents Attorney General Ashcroft in the New York case challenging this Act; is that right?

A. Correct. Correct.

Q. And this was during the time you were discussing with the Government the possibility that you would serve as one of their witnesses in this case; right?

A. I'm not even sure that we were discussing being a * * *.

* * * * *

[1741] determination as to which procedures are covered by the Act and which are not?

A. Well, I would be concerned if I didn't know the context to which he made that statement.

Q. Doctor—

A. Or in which he made that statement.

MS. SMITH: May I approach?

THE COURT: Yes.

BY MS. SMITH:

Q. Doctor, I have just handed you a copy of your deposition, and if you would turn to page 67, line 9. Do you guys have that?

MR. COPPOLINO: Yes.

BY MS. SMITH:

Q. And tell me when you get there.

A. I'm there.

Q. And, Doctor, the question there is if you understood that the person in the Justice Department responsible for enforcement of the ban had testified under oath that there has been no determination as to what procedures are covered and what are not, would that

concern you? Ms. Gowan: Objection. Answer: Yes. That was your testimony; right?

A. That's what I said, correct, but again, I don't think that my two statements are inconsistent.

Q. Okay. Thank you, Doctor. By the way, Doctor, did you [1742] know the statements of the government's attorneys in their legal briefs they submit in this type of case are not binding on the people who actually enforce the law?

MR. COPPOLINO: Objection.

THE WITNESS: Well, if I did, I would probably be in law school.

THE COURT: I think that the objection is good. The witness can't—The objection is sustained. Go ahead.

BY MS. SMITH:

Q. Doctor, you believe that a zealous prosecutor could interpret the Act as banning D & Es on 14-week fetuses with lethal anomalies which would place an undue burden on women seeking abortion in the second trimester; don't you?

A. I think it would depend very much on the final determination of the intent and deliberate aspects of the Act.

Q. Doctor, I believe you testified this morning that you find it distressing that the Act's imposition of criminal penalties—Withdrawn. Let me try that again. Doctor, I believe you testified this morning that you find distressing the Act's imposition of criminal penalties on physicians who perform partial-birth abortions; correct?

A. Correct.

Q. In fact, you think the imposition of further criminal penalties further unravels the physicians' social contract [1743] with their patients; don't you?

A. Absolutely.

Q. By social contract, you mean the ability of the patient and the physician to review all appropriate medical options and make an informed decision about the best course of treatment; is that right?

A. It's a little bit more involved than that. You would have to be a fan of my editorials to know what I was talking about. What I was referring to were a series of editorials that actually had to do with the intrusion of various social and regulatory agencies and social patterns and so forth on the delivery of health care, and they ranged from the recently-enacted HIPA regulations to the tort reform crisis, and in the context of a professional liability crisis, the lack of trust and faith that had occurred between patients and their doctors that was exploded by, obviously, not, of course, anyone in this room, but by certain unscrupulous attorneys that filed lawsuits that could be only considered, since somebody presented them, are never found against the defendant to be necessary, that there was a lack of trust and faith that had occurred and developed and was, in fact, increasing between patients and their doctors, and it takes many forms and many manifestations, and it's the contract by which the patient comes to their doctor and expects the doctor to do their very best for the patient, to treat the [1744] patient with both autonomy and beneficence, and the patient, in turn, agrees to be treated by the doctor, to accept the doctor's not omnipotent, not always going to be

errorless in his management, that the doctor will be teaching residents and medical students, and that the doctor will also ask her to be involved in research projects, and all those things are framed and breaking down, so it's a social contract that really facilitates not only health care delivery but particularly academic health care delivery.

Q. Thank you, Doctor. Doctor, you also think it's entirely unconscionable for Congress to encourage civil suits such as those allowed under the Act; don't you?

A. Yes. Red meat in front of a wolf.

Q. I'm going to ask you a few questions about your abortion practice at NYU now, Doctor. You told us you were chair of the OB/GYN department there from 1995 to 2002; is that correct?

A. That's correct.

Q. And as chair, you hired physicians who performed abortions; is that correct?

A. That's correct.

Q. And as you testified, one of those physicians actually performed the intact D & E procedure; correct?

A. Correct.

Q. And as chair, you're confident that that physician would [1745] always have provided the procedure she felt was safest; aren't you?

A. Correct.

Q. And, in fact, you wouldn't have allowed any unsafe procedures to be performed in your department; is that right?

A. It would have been very much a violation of my obligation, correct.

Q. And in your last year at NYU, approximately 900 abortions were performed; is that right?

A. That's what I have been told.

Q. And approximately, and you don't have any reason to doubt that; do you, Doctor?

A. None at all.

Q. And approximately one-third of these were performed in the second trimester?

A. Correct.

Q. And of the second trimester abortions, approximately 25 to 35% were intact D & Es; right?

A. Correct.

Q. So doing the math, that's approximately—I hope I get this right. I know I made an error in math recently, but approximately 75 to a hundred procedures a year were performed using the intact procedures; is that right?

A. Correct.

[1746]

Q. Doctor, you also contemplate if the new director you're seeking to hire at Yale wishes to do so, the intact D & E will be performed and taught at Yale as well; right?

A. Correct.

Q. Doctor, you agree, don't you, that prior to 20 weeks, D & Es appear to be associated with fewer significant complications than medical induction abortions?

A. Define significant.

Q. Well, why don't we go to page 30 of the deposition, line four. The question was: Now, just to go back to your draft editorial piece which you thought was accurate at the time you wrote it. Is it still your opinion your findings set forth in the Act failed to provide rigorous evidence that the procedure proposes greater health risks than alternatives. Ms. Gowan: Objection. Answer: I actually spent a good deal of time thinking about this. I think that the answer is that my view of the topic is as follows: That prior to 20 weeks, there seems reasonable evidence that D & Es are associated with fewer complications than medical abortions, and that 20 weeks, medical abortions appear to be associated with fewer significant complications than D & Es. Is that right?

A. So I'm defining significant.

Q. Yes, and I guess you didn't use significant when we talked about prior to 20 weeks; did you?

[1747]

A. I'm really not trying to be, believe me, a wordsmith about this. I guess my point would be that I think there is very little doubt that the occurrence of retained placentas and potentially infection are more common with medical abortions before 20 weeks. That's not to say that the occurrence of catastrophic complications, hysterectomies from perforations and so forth, are more common in medical abortions. I don't think so. I think they actually are more common in surgical abortions, so they are sort of significant, and there's really significant complications, but in general, I think I'll stick with my deposition.

Q. Okay. Thank you, Doctor. And Doctor, you believe that after 20 weeks, D & Es, intact D & Es and medical induction abortions are comparable in terms of safety; don't you?

A. I mean, yes, for our purposes.

Q. And even though the procedures are comparable in terms of safety, most abortions performed at or after 21 weeks are surgical abortions and not medical induction abortions; correct?

A. Correct.

Q. And one of the reasons for this is because it's unpleasant for the patient to be admitted to the hospital and go through labor instead of having a 30-minute surgical procedure; isn't that right?

A. That seems to be the argument.

[1748]

Q. And you agree that patient preference based on the length of the procedure or comfort level is an important consideration in choosing a procedure; don't you?

A. Correct.

Q. And a woman should be given an option to have an induction or a surgical abortion after 20 weeks and before viability; isn't that correct?

A. Barring some contraindication to either procedure.

Q. And inductions are generally not recommended before 15 weeks; is that right?

A. Well, I mean, the field is actually evolved to the point where the use of Mifepristone plus Misoprostol

probably permits medical terminations from four weeks to term, so it's, you know, theoretically possible. I think people tend to favor early medical abortions and later medical abortions and tend to favor suction curettage in between, so, you know, from, let's say, seven to 12, 14 weeks, the vast majority of those terminations are done by suction D & E, suction D & C.

Q. And before 15 weeks you wouldn't recommend a medical abortion; would you, Doctor?

A. Probably not.

Q. Probably not or no?

A. Well, probably not. I think there is a growing literature, and it would be worth following it, but at this * * *.

* * * * *

[1750] induction abortions; right?

A. Correct.

Q. When a physician sets out to do any D & Es, you agree that he or she intends to make as few passes into the uterus as possible with instruments; correct?

A. Correct.

Q. And intact D & E itself does involve fewer passes of instruments into the uterus; right?

A. By definition.

Q. And fewer passes with instruments would mean less risk that the uterus will be perforated or lacerated; right?

A. That remains to be proven.

Q. Doctor, will you turn to your deposition at page 105, line 23?

A. What page?

Q. 105, line 23. Question: Are you there, Doctor? I'm sorry.

A. Line 23. Yes.

Q. Question: And fewer passes would mean less risk of infection or perforation or laceration; right? Ms. Gowan: Objection. Answer: Correct. Was that your testimony, Doctor?

A. Certainly in the context of a D & E. I think if you keep reading, you get the rest of my answer.

Q. Fewer passes with instruments also reduces the risk of [1751] infection, right, with D & E?

A. Yes.

Q. And is there any reason to think that that wouldn't be true for an intact D & E?

A. No.

Q. Okay. And in an intact D & E procedure, the uterus and cervix are less likely to be exposed to sharp fetal bone and skull fragments; correct?

A. Correct.

Q. Doctor, you've stated you have some concerns about the conversion of the fetus to a breech position; is that right?

A. Correct.

Q. But the Act also prohibits procedures that do not involve conversion to a breech position; correct?

A. Correct.

Q. And moreover, Doctor, the documented risks of internal podalic version relates to periods closer to term when the uterine wall is thinner; right?

A. Certainly as regards the findings, absolutely.

Q. Doctor, you discussed earlier an opinion that you gave at your deposition in which you agreed that clearly, there is a significant body of medical opinion that in some circumstances for some women, an intact D & X may be safer than the available abortion options. Could you turn to page 159 of your deposition at line 20?

[1752]

A. This is designed, obviously, to drive me insane with the incredibly small type here. Okay. Sorry.

Q. It's designed to make it easier so that it's not this thick.

A. Absolutely. I'm sorry. What line?

THE COURT: Don't believe her, Doctor.

MS. SMITH: Line 20.

THE COURT: You were right the first time.

THE WITNESS: Okay. Yes. I'm sorry.

BY MS. SMITH:

Q. The question was, based on the review you have made of the various declarations submitted by certain plaintiffs, these cases on the basis of the policy statement in 1997 and again in 2002 from ACOG, is it your view that there is a significant body of medical opinion that in some circumstances for some women, an intact D & E may be safer than the available abortion options?

Ms. Gowan: Objection. Answer: There clearly is. That was your testimony at the deposition; right, Doctor?

A. Right.

Q. And your—

A. Big printing?

MS. SMITH: Would you prefer?

THE WITNESS: I'm getting older. I'm probably all right, but we'll take it. I need to invent like * * *.

* * * * *

[1757] six/sevenths, the fetus is essentially an equal partner in this care, and that between 20 and 24 weeks, the physician should do everything they can possibly do while respecting a woman's reproductive choices and autonomy to minimize trauma and pain to the fetus as long as it doesn't endanger the mother's health.

Q. Thank you, Doctor. Now, I understand you believe the risk of injection of Digoxin or KCL are, I think you said, are presumably negligible?

A. Correct.

Q. But aren't they—But first of all, they are not zero. You would agree with me?

A. No, they are not zero.

Q. Right. And you would agree that they are higher for a woman with a viral infection, such as HIV or hepatitis; wouldn't you?

A. I would certainly not want to do it in a patient with HIV or hepatitis.

Q. Thank you, Doctor. Doctor, both the intact D & E and the D & E procedure involve dilation of the cervix; right?

A. Correct.

Q. And in some cases, the cervix will dilate more than others even with the same cervical preparation; is that correct?

A. Correct.

[1758]

Q. If the physician achieves significant dilation of the cervix, he or she may perform an intact D & E; right?

A. They may opt to do that, correct.

Q. In fact, the decision of whether to attempt an intact removal was made at NYU during the performance of a procedure depending in part on the extent of the cervical dilatation achieved; right?

A. Correct.

Q. And with respect to induction abortions, Doctor, the procedures that begin as induction abortions sometimes fail; isn't that right?

A. Correct.

Q. And in performing a pre-viability induction abortion, it sometimes happens that the fetus is partly expelled in a breech position, but before the head is delivered, the woman experiences excess bleeding, for example?

A. Correct.

Q. And in that case, one of the options in the physician's armamentarium, as you put it, would be to compress the calvarium with forceps; isn't that right?

A. Correct.

Q. And the fetus could have indications of life before the calvarium was compressed; isn't that correct?

A. Right.

Q. When a physician begins an induction shown abortion, the [1759] physician knows at the outset that these circumstances may occur and would necessitate the instrumentation you just described; correct?

A. Correct.

Q. Similarly, Doctor, in a D & E, when a physician begins a procedure pre-viability, attempting to take the fetus out in as large pieces as possible, but not specifically intending to do an intact procedure, the fetus may be pulled through the cervix until the after coming head is obstructed; isn't that right?

A. Or may come right out.

Q. Or it may come right out. But in the circumstance where the after coming head is obstructed, one of the options in the physician's armamentarium would be to compress the calvarium with forceps in order to remove the fetus just as in the induction?

A. Correct.

Q. And the fetus could have indications of life before the calvarium was compressed; right?

A. Right.

Q. When a physician begins a D & E, the physician may know at the outset that circumstances may occur and would necessitate this instrumental completion that you have just described; right?

A. Correct.

* * * * *

[1761]

A. I'll believe it when I see it.

Q. That's a promise. But first before we end—

A. Trust and verify as Ronald Reagan used to say, but okay.

Q. I just had a couple of questions about the Chasen study first.

A. Um-hm. That's interesting.

Q. Yes. Well, given that you've testified about it, I will go there too. As you noted, I believe you testified that the risk of morbidity from abortion, while very low, they increased each week of gestation; right?

A. Correct.

Q. And as I think you also noted in the Chasen study, the median gestational age of the women receiving intact D & Es was 23 weeks while the median gestational age of women receiving D & Es in a nonintact procedure was 21 weeks; right?

A. Correct.

Q. And therefore, you would expect, wouldn't you, that the rates of complications of the intact D & E group would be higher; wouldn't you?

A. Yes.

Q. But they weren't higher; were they?

A. No.

Q. Doctor, you also testified that you had an initial concern about the risk of spontaneous preterm birth in the [1762] intact group because the spontaneous preterm birth occurred in two of the 17 subsequent births in the intact group that they were able to follow and in

two of 45 of the subsequent births in the nonintact group; right?

A. Correct.

Q. And as you noted, the difference between two of 17 and two in 45 is not statistically significant. The numbers are too small; right?

A. Correct.

Q. And as I think you also testified, the two women in the intact group who had spontaneous preterm birth had risk factors; right?

A. Also correct.

Q. And, in fact, the reason that they had abortions in the earlier pregnancy was precisely because they had premature ruptured membrane or advanced cervical dilatation at 23 weeks. Both of these are risk factors for premature labor in future pregnancy; isn't that right?

A. I think I covered all that.

Q. Okay. Thank you, Doctor. I think you covered most of it. I just had a couple of points I wanted to clarify. But now I really am on my last page. Doctor, you stated that your personal belief is that between 20 and 24 weeks, efforts should be made to avoid fetal pain because of the potential there might be fetal pain at that gestational age; [1763] right?

A. Right.

Q. But there is no basis to distinguish between D & E and D & X from the perspective of fetal pain; is there?

A. None whatsoever.

Q. And the Act doesn't require that anesthesia be given to a fetus between 20 and 24 weeks or at any gestational age in a D & E that did not follow the course described in the Act; right?

A. Unfortunately, true.

Q. And, Doctor, you also stated on direct that you don't believe that restrictions should be placed on physicians performing abortions prior to 20 weeks at all?

A. That's correct.

Q. Right? But the partial-birth abortion act is not limited to abortions performed prior or after 20 weeks; is it?

A. Also correct.

Q. And finally, Doctor, you testified on direct that based on the information currently available, you do not believe that partial-birth abortion should be prohibited at Yale; isn't that right?

A. That's correct.

MS. SMITH: Just one moment, Your Honor. I have no further questions, Your Honor. Thank you, Doctor.

[1764]

THE COURT: Redirect?

[Dr. Charles Lockwood—Redirect]

BY MR. COPPOLINO:

Q. Just a few more questions, Dr. Lockwood. You testified that you regarded Drs. Westhoff and Chasen as respected OB/GYNs; correct?

A. Correct.

Q. Do you know Dr. Watson Bowes?

A. I do.

Q. Do you regard Dr. Watson Bowes as a respected OB/GYN?

A. I do.

Q. Do you know Dr. Steve Clark from Salt Lake City?

A. Very well.

Q. Do you regard Dr. Steve Clark as a respected OB/GYN?

A. I do.

Q. He is a maternal fetal specialist as well; right?

A. Absolutely.

Q. Quite an expert in high risk obstetrics; right?

A. Well, he is the expert in critical care obstetrics.

Q. Ms. Smith asked you some questions regarding the NYU practice again, and I just want to make sure that's clear for the record. Did you knowingly allow D & X to occur at NYU on your watch?

A. I feel like it's a court martial. Well, I would have if I had known, but I did not know.

[1765]

Q. You did not know it was occurring?

A. That's correct.

Q. Did you agree with anyone at NYU who determined that the procedure was safe with respect to long-term consequences?

A. Well, I never, the issue was never raised, so—

Q. Ms. Smith asked you about the comparability between D & E medical induction and D an X, and I believe you said that they have comparable rates of safety after 20 weeks; is that correct?

A. Yes.

Q. Do we know the true comparability of the D & X procedure, long term, since it's never been studied?

A. No.

Q. Now, related to that, Doctor, the Chasen study on the data on pre-term birth, you said, I believe when I questioned you, that that causes you concern that requires further study; is that correct?

A. I had concern before I read it and I still have the concern after I read it.

Q. And we won't know until the issue is studied whether the pre-term birth is a real problem for the D & X procedure; is that correct?

A. Correct.

Q. And suppose intuition is wrong and the D & X procedure causes a significant increase in pre-term birth. Wouldn't [1766] that be a potentially disastrous outcome for the many women who are undergoing that procedure?

A. Especially from my perspective.

Q. Ms. Smith asked you a question about the dilation process for a D & X. I want a follow up question on that. Do you agree that a physician can make a decision to attempt a deliberate and intentional D & X after assessing dilation?

A. I think so, yes.

Q. And, Doctor, is it your view that anecdotal evidence and intuition is a sound way to practice medicine when there are other safe, studied alternative procedures available?

A. I agree with almost everything I said in the deposition so far, so I would agree with that one also.

Q. Doctor, even though you agree that the D & X procedure might have comparable safety indications to alternatives, do you also agree that it's never necessary to use that procedure to preserve maternal health in light of other safe alternatives?

A. I would agree with the caveat being that there may be some circumstance that I'm not aware of. I suppose HIV positive, so on, so on and so on, that you never say with a hundred percent certainty, you know, an HIV-positive patient with a placenta previa, you know, you can create a scenario that eventually I'll cry uncle, but for all intents and purposes, the answer is correct.

[1767]

Q. And in those cases in which you would cry uncle, the availability of a safe KCL or Digoxin injection would be available to you?

A. Not in the case they raise of a patient that's HIV positive that has detectable viral loads.

Q. All right. Ms. Smith called your attention to a couple of statements in your deposition. I would like to go back to those if we could. Let's see. Let's do the instrument passes first on page 106 of your big print deposition.

A. I really do feel old.

Q. Ms. Smith asked you, called your attention to the question and answer starting on the bottom of 105, line 23, and fewer—in which the question is: And fewer passes would mean less risk of infection or operation or laceration; right? Ms. Gowan: Objection. Your answer: Correct, and then when you testified today, I believe you said keep reading. So let's keep reading. Let's take a look at line 2 of page 106. Question: Why wouldn't that constitute an advantage in that circumstance of a D & X over a D & E? Answer: I think the big issues, the big risks with intact D & X as defined by ACOG here, for example, are the internal podalic version which is potentially a single, although it's a single pass, theoretically, it may not be, but presume for a minute that it is, would create greater torsion and greater potential risk of lateral laceration and * * *.

* * * * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

No. 4:03CV3385

LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., AND JILL L. VIBHAKAR, M.D., ON BEHALF OF THEMSELVES AND THE PATIENTS THEY SERVE, PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES, AND HIS EMPLOYEES, AGENTS AND SUCCESSORS IN OFFICE, DEFENDANT

DEFENDANT'S NOTICE OF APPEAL

NOTICE IS HEREBY GIVEN that the defendant, John Ashcroft, Attorney General of the United States, hereby appeals to the United States Court of Appeals for the Eighth Circuit from this Court's Order and Judgment dated September 8, 2004, and all earlier rulings and interlocutory orders that gave rise to and/or produced that judgment.

Dated this 27th day of September.

Respectfully submitted,

PETER D. KEISLER
Assistant Attorney General

MICHAEL G. HEAVICAN
United States Attorney

PAUL D. BOESHART #10365
Assistant U.S. Attorney
District of Nebraska
(402) 661-3700

THOMAS R. LEE
Deputy Assistant Attorney
General

/s/ ANTHONY J. COPPOLINO
ANTHONY J. COPPOLINO
Special Litigation Counsel

TERRY M. HENRY
Senior Trial Counsel

PREEYA M. NORONHA
ANDREW I. WARDEN
Trial Attorneys
United States Department of
Justice
Civil Division
Federal Programs Branch
20 Massachusetts Ave., N.W.
Room 6102
Washington, D.C. 20530
Tel: (202) 514-4782
Fax: (202) 616-8460
E-mail: tony.coppolino@usdoj.gov

Attorneys for Defendant

CERTIFICATE OF SERVICE

I hereby certify that, on September 27, 2004, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notification of such filing to the following counsel for plaintiffs:

Jerry M. Hug
Priscilla J. Smith
Janet L. Crepps
Suzanne Novak
Nan E. Strauss

/s/ PREEYA M. NORONHA
PREEYA M. NORONHA

[Pl. Exh. No. 27]
[Gov't Exh. No. 27a]

Dilation and evacuation of ≥20 weeks: Comparison of Operative technquies

SEALED
[Prior to Publication]

Stephen T. Chasen, MD
Robin B. Kalish, MD
Meruka Gupta
Jane E. Kaufman, MD
William K. Rashbaum, MD
Frank A. Chervenak, MD

Department of Obstetrics and Gynecology
Weill Medical College of Cornell University
New York, NY

Corresponding Author:
Stephen T. Chasen, MD
525 East 68th Street, Room J130
New York, NY 10021
(212) 746-3274
(212) 746-3378 (fax)
stchasen@ med.cornell.edu

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In patients undergoing surgical abortion at ≥ 20 weeks, dilation and evacuation and intact dilation and extraction result in similar complication rates.

Objective: The objective of this study is to compare the relative safety of two techniques for surgical abortion late in the second trimester.

Study Design: Retrospective review of patients who underwent surgical abortion at ≥20 weeks' gestation at our hospital from 6/1999-6/2003. Records were reviewed to determine if the technique used was dilation and evacuation or intact dilation and extraction. Subsequent pregnancies at our hospital were identified, and obstetric outcomes were recorded. Categorical data were compared with Fisher's exact test and Chi-square analysis. Continuous data were compared with Mann-Whitney U test.

Results: 383 patients met inclusion criteria. Intact dilation and extraction was performed in 120 cases, and dilation and evacuation was used in 263. Intact dilation and extraction was associated with higher parity, later gestational age, and more preoperative cervical dilation. There was no difference in procedure time or estimated blood loss in the two groups. Complications occurred in 19 cases (5.0%), and occurred with similar frequency in the two groups. We identified 62 subsequent pregnancies. There were no second-trimester miscarriages. Spontaneous preterm birth occurred in 2 of 17 (11.8%) pregnancies in the intact dilation and extraction group, compared to 2 of 45 (4.4%) in the dilation and evacuation group (p=0.30).

Conclusion: Outcomes appear similar between patients undergoing dilation and evacuation and intact dilation and extraction after 20 weeks' gestation. Subsequent

obstetric outcomes are similar between the two groups. The technique for surgical abortion should be determined by the physician based on intraoperative factors.

Key Words: Abortion, Dilation and evacuation

In the United States, induced abortion late in the second trimester is uncommon. In 1999, 9,643 abortions were performed at ≥21 weeks' gestation, representing only 1.5% of total abortions reported.[1] Dilation and evacuation is the most common method used for second trimester abortion,[1] and is considered the safest abortion technique in the second trimester.[2-5]

Dilation and evacuation involves preoperative dilation of the cervix using osmotic dilators, such as laminaria, which are placed in the cervix for one or more days prior to operative evacuation. All published reports of dilation and evacuation have described the use of grasping forceps to remove the fetus and placenta. Using forceps, fetal parts are grasped, and the fetus and placenta are disarticulated as they are removed. Low complication rates for this procedure have been reported.[2-5]

A variant of dilation and evacuation can be performed when sufficient cervical dilation is present. In these cases, the fetus is delivered via breech extraction. If the fetus is not in the breech presentation, internal podalic version may be performed. In most cases, after delivery of the body, the fetal head will become lodged in the cervix, and cranial decompression with suction must be performed to complete delivery. This procedure has been referred to as intact dilation and extraction, or D&X. There is no published data regarding the frequency or complication rate of this procedure. Despite this, some have stated that this

procedure poses serious maternal risks and is less safe than dilation and evacuation.[6,7]

The objective of this study is to evaluate the relative safety of dilation and evacuation and intact dilation and extraction in patients undergoing surgical abortion late in the second trimester.

Materials and Methods

This study was a review of patients who underwent surgical abortion at ≥20 weeks' gestation at the New York Weill Cornell Medical Center from June 1996 to June 2003. All procedures included in this study were performed by one of two physicians (STC and WKR) who are skilled in both techniques, dilation and evacuation and intact dilation and extraction. Institutional Review Board approval was obtained for this study.

Gestational age was confirmed by ultrasound in all cases. All cases ≥24 weeks' gestation were performed due to *fetal* demise. Dilation of the cervix was achieved with insertion of laminaria. Laminaria were placed preoperatively on two consecutive days, unless the cervix was sufficiently dilated at the initial examination. Women who went into labor following laminaria placement and delivered without dilation and evacuation of intact dilation and extraction were not included in this study.

The surgical technique was determined when the patient was examined under anesthesia, and was based on cervical dilation and fetal position. Both physicians performing these procedures used similar criteria in determining the optimal surgical technique.[8] All cases were considered complete when, after evacuation of the fetus and placenta, hemostasis was apparent after sharp and suction curettage. Blood loss was estimated

by the surgeon. Procedures were performed in an ambulatory setting, unless patients had been hospitalized prior to the procedure for medical or obstetric conditions. The type of anesthesia used for the procedure, general, regional, or intravenous sedation, was at the discretion of the anesthesiologist. Intraoperative ultrasound guidance was not routinely used.

Operative reports were reviewed to determine the technique used in each case. If the fetus was delivered intact in the breech presentation to the level of the umbilicus or higher, the procedure was considered an intact dilation and extraction, whether or not the entire fetus was removed intact or decompression of the head was required. In some cases, the presenting fetal head was well applied to the cervix, and was initially decompressed with suction, followed by intact delivery of the fetus. These cases were also considered intact dilation and extractions, as disarticulation with forceps was not required. All other cases, which were performed with multiple insertions of forceps, were categorized as dilation and evacuation.

Complications included any situation requiring unplanned intervention. These included unplanned hospital admission, repair of any genital tract lacerations, return to the operating room for additional procedures, and blood transfusion. Subsequent pregnancies at our hospital were identified from review of medical records. We did not obtain follow-up on patients routinely, so subsequent pregnancies with prenatal care obtained elsewhere were not included in this analysis. 38 patients in this series, 26 of whom underwent dilation and evacuation and 12 of whom underwent intact dilation and extraction, were included in a prior publication

describing obstetric outcome after second trimester abortion.[7]

Demographic characteristics and outcomes were compared based on operative technique. Categorical variables were analyzed using two-tailed Fisher's exact test and Chi-square analysis where appropriate. Mann-Whitney U test were used to analyze continuous variables, which were not normally distributed. Analysis was done using SPSS 11.0 (Chicago, III). A p value <0.05 was considered significant.

Results

383 patients met inclusion criteria. Intact dilation and extraction was performed in 120 cases (31.3%), and dilation and evacuation was used in 263 (68.7%). Demographic [7] characteristics of the two groups are listed in Table I. Intact dilation and extraction was associated with the later gestational age, higher parity, and younger maternal age.

Indications for surgical abortion are listed in Table II. Preterm cervical dilation and/or preterm premature rupture of membrances (PPROM) were more common in those who underwent intact dilation and extraction. Abnormal fetal karyotype was more common in those who underwent dilation and evacuation.

Intraoperative variables are listed in Table III. Overall, laminaria were used in 96.1% of cases. Laminaria were less likely to be used in patients undergoing intact dilation and extraction. All 15 patients in whom laminaria were not used had preterm cervical dilation. Preoperative cervical dilation was greater in those who underwent intact dilation and extraction. No differences were noted in procedure time or estimated blood loss between the two groups.

In the entire group of 383 patients, complications occurred in 19 cases (5.0%). Complications occurred with similar frequency in the dilation and evacuation and intact dilation and extraction groups (4.9% vs. 5.0%; p = 1.0). The 6 complications occurring in the intact dilation and extraction group included 4 gential tract lacerations (3 cervical mucosal lacerations and one perineal laceration) noted and successfully repaired at the time of surgery; 1 case of excessive bleeding requiring return to the operating room on the day of surgery for curettage; and one patient readmitted due to heavy bleeding on postoperative day 13 who underwent dilation and curettage for retained placenta.

Complications in patients undergoing dilation and evacuation included 4 gential tract lacerations (2 cervical lacerations and 2 labial lacerations) noted and successfully repaired at the time of surgery; 2 cases of excessive bleeding requiring return to the operating room on the day of surgery (for curettage in 1 case, and repair of cervical lacertions in 1 case); 2 postoperative admissions for intravenous antibiotics due to endometritis; 1 admission for observation following excessive bleeding; and 1 admission due to severe nausea from general anesthesia.

Three patients, all of whom underwent dilation and evacuation, had complications requiring admission to the surgical intensive care unit. One patient, with a fetal demise, had an amniotic fluid embolus with disseminated intravascular coagulation requiring transfusion of blood and clotting factors. One patient was diagnosed with sepsis and pulmonary embolus. One patient had a uterine perforation at the site of a cesarean delivery scar, and required exploratory laparotomy and blood transfusion.

45 women (17.1%) in the dilation and evacuation group and 17 women (15.0%) in the intact dilation and extraction group had a subsequent pregnancy and received care at our medical center. There were no second-trimester spontaneous abortions in either group. Spontaneous preterm birth occurred in 2 of 17 (11.8%) pregnancies in the intact dilation and extraction group compared to 2 of 45 (4.4%) in the dilation and evacuation group (p=0.30). Both spontaneous preterm births in the intact dilation and extraction group occurred in women at high-risk for prematurity: one woman, who underwent intact dilation and extraction due to PPROM at 23 weeks' gestation, subsequently delivered at 32 weeks; the other underwent intact dilation and extraction at 23 weeks' gestation due to cervical incompetence with advanced cervical dilation, and subsequently delivered at 35 weeks.

Discussion

Based on this series of 383 patients, surgical abortion late in the second trimester is a safe procedure. There were low rates of complications in procedures with either technique.

As described in a prior publication,[5] we did not see a high rate of spontaneous preterm birth in subsequent pregnancies in those who received obstetric care at our medical center.

Because this study was retrospective, we cannot state that one technique is superior to the other. Procedures performed with intact dilation and extraction occurred at later gestational ages and with more preoperative cervical dilation. While more advanced gestation might be expected to increase complication rates, more preoperative cervical dilation might be expected

to facilitate these procedures. Differences between maternal age, gestational age, and indication for surgical abortion were noted between the two groups. The difference in gestational age may be due to changes in the cervix that occur as pregnancy progresses. With advancing gestation, the cervix may be more likely to respond to laminaria placement with greater dilation. Intact dilation and extraction requires more dilation, as the intact fetus cannot pass through a minimally dilated cervix. In addition, more women in the intact dilation and extraction group underwent abortion due to premature cervical dilation or PPROM. The incidence of these conditions increases with advancing gestation, and the spontaneous cervical dilation occurring in these cases probably facilitated intact dilation and extraction.

The difference in maternal age is likely due the higher rate of fetal aneuploidy in the dilation and evacuation group. Amniocentesis is typically performed at 16-18 weeks, and advanced maternal age is the most common indication. Most cases of fetal aneuploidy are identified by 20 weeks. This could explain why those in the dilation and evacuation group were older, and underwent abortion at earlier gestational ages.

Our approach of performing intact dilation and extraction when possible is intended to minimize the use of forceps in extracting the fetus. We believe that use of forceps to grasp the fetus can cause inadvertent trauma to the uterine wall. At these gestational ages, evacuation of a fetus can require multiple insertions of forceps, and intact dilation and extraction avoids this. Though we believe our low complication rate validates our approach, we acknowledge that the retrospective nature of this study precludes us from concluding with

certainty that intact dilation and extraction prevented adverse outcomes.

Another important limitation is the relatively small number of patients receiving prenatal care at our hospital in subsequent pregnancies. Most patients returned to their referring obstetrician for future obstetric care, and we were unable to assess subsequent pregnancy outcomes of patients delivered at other institutions. We believe that significant bias as a result would be unlikely, though we cannot be certain that outcomes in pregnancies followed at our hospital are representative of outcomes in all subsequent pregnancies. Though we are reassured by the low number of complications in subsequent pregnancies in both groups, we acknowledge our lack of power to conclude that subsequent pregnancy outcomes are not different.

Some have stated that intact dilation and extraction poses serious risks to the health of a woman beyond the risks associated with dilation and evacuation. Such putative risks include higher rates of cervical incompetence, uterine rupture, abruption, amniotic fluid embolism, and trauma to the uterus.[6,7] We are not aware of any published data supporting these statements. In our patients, the overall rate of complications was comparable between those undergoing dilation and evacuation and intact dilation and extraction. No patient undergoing intact dilation and extraction experienced uterine rupture, amniotic fluid embolism, or required blood transfusion. Because our approach is to perform intact dilation and extraction when possible based on cervical dilation and fetal position, it is unlikely that intact dilation and extraction could have been performed in these patients undergoing dilation and evacuation who experienced severe complications.

In conclusion, our data affirm that abortion after 20 weeks' gestation with intact dilation and extraction appears to have similar complication rates as dilation and evacuation when performed by experienced physicians. The observed complication rates and subsequent obstetric outcomes appear comparable between the two techniques. In accordance with the American College of Obstetricians and Gynecologists (ACOG) statement of policy,[9] our data supports that the most appropriate technique for surgical evacuation of pregnancy after 20 weeks' gestation should be based on intraoperative factors. Attempts to regulate intact dilation and extraction based on concern for maternal well-being cannot be supported by available evidence.

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Table I. Demographic characteristics of patients undergoing dilation and evacuation.

	D&E (n=263)	D&X (n=120)	p value
Median Maternal Age	34 years	32 years	0.01*
(range)	(16-45)	(12-43)	
Median Parity	0	1	0.04*
(range)	(0-7)	(0-5)	
Median Gestational Age at dilation and evacuation	21 weeks	23 weeks	<0.001*
(range)	(20-27)	(20-25)	
Prior Vaginal Delivery	81 (30.8%)	50 (41.7%)	0.05†
Prior Cesarean Delivery	49 (18.6%)	26 (21.7%)	0.49†
Multifetal Pregnancy	13 (4.9%)	8 (6.7%)	0.48†

*Mann-Whitney U test

†Fisher's exact test

D & E = Dilation and evacuation

D& X = Intact dilation and extraction

Table II. Indication for dilation and evacuation*

Indication for dilation and evacuation	D&E (n=263)	D&X (n=120)	p value†
Abnormal fetal karyotype	112 (42.6%)	33 (27.5%)	0.005
Structural fetal abnormality	96 (36.5%)	47 (39.2%)	0.65
Intrauterine fetal demise	27(10.3%)	14 (11.7%)	0.72
Premature cervical dilation/PPROM	14 (5.3%)	20 (16.7%)	0.001
Other	22 (8.4%)	13 (10.8%)	0.45

*Some patients had more than one indication

†Fisher's exact test

D & E = Dilation and evacuation

D & X = Intact dilation and extraction

Table III. Intraoperative variables

	D&E (n=263)	D&X (n=120)	p value
Laminaria	259 (98.5%)	109 (90.8%)	0.001*
Median Preoperative Cervical Dilation (range)	3 cm (0-6)	5 cm (2-10)	<0.001*
Anesthesia			
General	92 (35.05%)	53 (44.2%)	0.22[0]
Regional	9 (3.4%)	3 (2.5%)	
Local/Conscious Sedation	162 (61.6%)	64 (53.3%)	
Median Procedure Time (range)	22 minutes (6-60)	22 minutes (6-45)	0.54*
Median Estimated Blood Loss (range)	100 ml (40-1500)	100 ml (20-1200)	0.38*

*Mann-Whitney U test

†Fisher's exact test

[0]Chi-square anlaysis

D & E = Dilation and evacuation

D & X = Intact dilation and extraction

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

Civil Action Number 4:03CV3385

LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D.,
WILLIAM H. KNORR, M.D., AND
JILL L. VIBHAKAR, M.D., PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS OFFICIAL CAPACITY AS
ATTORNEY GENERAL OF THE UNITED STATES,
DEFENDANT

DEPOSITION OF JOANNA M. CAIN

Tuesday, Feb. 10, 2004

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

No. 03 Civ. 8695 (RCC)

NATIONAL ABORTION FEDERATION; MARK I. EVANS, M.D.; CAROLYN WESTHOFF, M.D., MSc; CASSING HAMMOND, M.D., MARK HELLER, M.D., TIMOTHY R.B. JOHNSON, M.D., STEPHEN CHASEN, M.D., GERSON WEISS, M.D., ON BEHALF OF THEMSELVES AND THEIR PATIENTS, PLAINTIFFS

v.

JOHN ASHCROFT, IN HIS CAPACITY AS ATTORNEY GENERAL OF THE UNITED STATES, ALONG WITH HIS OFFICERS, AGENTS, SERVANTS, EMPLOYEES, AND SUCCESSORS IN OFFICE, DEFENDANT

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

Civil Action No. C-03-4872 PJH

PLANNED PARENTHOOD FOUNDATION OF AMERICA, INC., AND PLANNED PARENTHOOD GOLDEN GATE, PLAINTIFFS

v.

JOHN ASHCROFT, ATTORNEY GENERAL OF THE UNITED STATES, IN HIS OFFICIAL CAPACITY, DEFENDANT

Deposition of JOANNA M. CAIN, called for examination pursuant to notice of deposition, on Tuesday, February 10, 2004, in Washington, DC, at the U.S. Department of Justice, 20 Massachusetts Avenue, NW, 7th Floor, at 9:16 a.m., before SARA EDGINGTON, a Notary Public within and for the District of Columbia, when were present on behalf of the respective parties:

SUZANNE NOVAK, ESQ.
Center for Reproductive Rights
120 Wall Street
New York, New York 10005
(917) 637-3615

On behalf of Plaintiff Center for Reproductive Rights

HELEN T. KRASNOFF, ESQ.
Planned Parenthood Federation of America
1780 Massachusetts Avenue NW
Washington, D.C. 20036
(202) 973-4890

On behalf of Plaintiff Planned Parenthood

CATHERINE WEISS, Esq.
ACLU Reproductive Freedom Project
125 Broad Street
New York, New York 10004
(212) 549-2640

On behalf of Plaintiff ACLU

ANTHONY J. COPPOLINO, Esq.
PREEYA M. NORONHA, Esq.
U.S. DOJ Civil Division
20 Massachusetts Avenue NW
Washington, D.C. 20530
(202) 514-4782

On behalf of Defendant

DANIEL B. EDELMAN, ESQ.
YABLONSKI, BOTH & EDELMAN
1140 Connecticut Avenue NW, Suite 800
Washington, D.C. 20036
(202) 833-9060

On behalf of the Witness and ACOG

SARA NEEDLEMAN KLINE, Esq.
PENNY RUTLEDGE, ESQ.
American College of Obstetricians and
Gynecologists
409 12th Street SW
Washington, D.C. 20024-2188
(202) 863-2581

On behalf of the Witness and ACOG

* * * * *

[120] be sure we reviewed.

[Examination by Mr. Coppolino:]

Q. You said it contained no statistical information or other material that you felt was appropriate.

A. We didn't use it by itself for that.

Q. Right. What was not—let me ask it this way: What material did you feel was appropriate to be considered by the task force?

A. We felt the numerous examples the task force itself could put on the table regarding their experience or need for this procedure, the textbooks, published information about the safety of D & E and this as a subset of D & E, and the significant background and experience of the people at the table, and also information about the safety and alternatives and the safety of alternatives.

Q. Okay. Thank you. Let's take a look at the other New York Times. This is an editorial titled "abortion politics." This is Exhibit 16, ACOG 0043.

This document was before the task force during your deliberations?

* * * * *

[177]

Q. And the task force understood, did it not, that this procedure was performed beginning at 18 weeks, the intact D&X procedure?

A. That it could be performed starting at 16 weeks.

Q. Did it have an understanding that it was being performed starting at 18 weeks?

A. The task force understood that intact D&X was one method of performing an abortion after 16 weeks.

Q. What did the task force discuss with respect to safety?

A. Numerous examples were raised by the members of the task force regarding different procedures in specific cases and issues of safety. For example would be triploidy, which is a form of cancer of the placenta often diagnosed in the second trimester with severe preeclampsia. In that case, the least amount of instrumentation possible of the uterine wall is desirable. So it is much safer for the woman to have an intact D&X to remove the molar pregnancy. So multiple examples were used to explore issues of safety at the time and in [178] comparison to other proedures.

Q. Does the statement at Exhibit 7, the draft proposed statement, does this statement reflect the conclusions of the task force with respect to intact dilatation and extraction?

A. Yes.

Q. Okay. Did the task force identify any study which discussed the relative safety of intact D&X versus another method of abortion?

A. No, not as we had described it for purposes of our debate.

Q. Did the task force identify any study on the relative safety of abortion procedures in general which it relied on in reaching its conclusions about this procedure?

A. The CDC data, the ongoing data documents, the safety.

Q. Of? In what way?

A. D&E second trimester abortions.

Q. Okay. And you mentioned the CDC data. What was it about the CDC data which informed the task force's view with respect to the safety of [179] intact D&X?

A. The overall safety in the second trimester.

Q. Was the task force aware that Dr. Grimes had written an article in the 1980s regarding the relative safety of abortion procedures?

A. I'm sure that members of the task force would have been aware since it probably was quoted also in the textbooks available.

Q. Did the task force specifically consider Dr. Grimes's study with respect to the relative safety of abortion procedures?

A. I don't remember.

Q. Well, what I'm asking you is, can you say that whatever it was as a separate study referenced in a textbook, the task force specifically considered the data found by Dr. Grimes in his study the relative safety of abortion procedures?

A. I can say that it's likely.

* * * * *

[194]

A. I don't know. This is a statement that was added by the entire executive board.

Q. Do you know if Dr. Gibbons was an advocate for adding this sentence?

A. I don't know if he was an advocate at the time of the executive board. It is very much in keeping with the sense and the discussion of the task force.

Q. Then why isn't it in the draft of the task force?

A. As I said, when Dr. Frigoletto and I discussed that, we came to the same conclusion, that we—because we had talked about it so much, to us, the "notwithstanding this conclusion, the decisions about a medical treatment based upon the woman's particular circumstances" covered that. It is a matter of phrasing. To us, we were already there. We assume in medicine that our choices are made for the life and the health of our patients.

Q. Why did the select panel find that there were no circumstances—why was the select panel unable to identify circumstances under which the [195] intact D&X procedure was the only option to save the life or preserve the health of a woman?

A. Because there are multiple procedures available. It was simply a factual statement. There are other things that are available. They may not be the best for that individual patient.

Q. Are you aware of any analysis or study—let's strike that and say, are you aware of any study which supports the conclusion that intact D&X may be the best or most appropriate procedure in certain circumstances?

A. I'm not aware of a study. I am well aware of multiple circumstances that an expert panel could identify at the time of the task force where it was clearly the best choice, including in my field, where the other options led to a higher likelihood of death or recurrence of disease.

Q. I'm going to ask you about that in a minute, but I just want to document a couple of facts first, if I can. To your knowledge, are there any studies documenting the statement in the final statement that the intact D&X procedure may be the * * *.

* * * * *

[219]

[Examination by Ms. Novak:]

Q. I'd like you to look at Exhibit 3, please, which is the 1997 ACOG statement of policy. We're going to look at 3, and then we're going to look at 4.

A. Okay. I have 4 which includes 3. There it is. Okay.

Q. Exhibit 3, do you recognize this document?

A. Yes.

Q. And what is it?

A. It is the statement on intact dilatation and extraction of the American College of OB-GYN.

Q. Have you seen it before today?

A. Yes.

Q. When did you first see it?

A. When we created it in the task force.

Q. And do you know who prepared this document?

A. The American College of OB-GYN.

Q. Were you a part of the task force that wrote it?

A. Yes.

Q. And when did you write it?

[220]

A. We wrote it October 5th and 6th, 1996.

Q. And was this document prepared in the normal course of ACOG's business?

A. Yes.

Q. Did the drafting of this statement go through the same general drafting processes of statements of policy at ACOG that you testified about earlier?

A. To my understanding.

Q. Was this statement adopted through the same general adoption processes for statements of policy at ACOG that you testified about earlier?

A. To my understanding.

Q. I'd like you to turn to Exhibit 4, please.

A. Yes.

Q. Can you look at that document and tell me whether you recognize it?

A. I recognize it.

Q. And what is the document?

A. It is the ACOG statement of policy as issued by the executive board, abortion policy.

Q. Have you seen it before today?

* * * * *

[222]

Q. And do you know why the intact D&X part of it was written?

A. Yes. It was in response to concerns expressed by the fellowship at that time regarding a poorly defined

procedure for partial-birth abortion and potential legislation.

Q. Was this document prepared in the normal course of ACOG's business?

A. To my understanding.

Q. And did the drafting of Exhibit 4 go through the same general drafting process of statements of policy at ACOG that you testified about earlier?

A. To my understanding.

Q. Was the statement adopted through the same general adoption policies for statements of policy at ACOG that you testified to earlier?

A. To my understanding.

Q. Does this statement reflect ACOG's current abortion policy?

A. To my understanding.

Q. What is the American College of [223] Obstetricians and Gynecologists?

A. The American College of Obstetricians and Gynecologists is a professional membership organization organized in 1951 that is concerned with professional practice and education in the health care of women.

Q. And in what forms does it demonstrate its dedication to the health of women? What type of work does it do?

A. Its missions are ongoing education of its membership, research and advocacy for the health care of women.

Q. Is it a nonprofit organization?

A. Yes, it is.

Q. And is it a membership organization?

A. Yes, it is.

Q. How many members does ACOG represent?

A. I believe it now represents over 44,000.

Q. And where are these members located?

A. Throughout the United States and adjacent countries, Canada, Mexico.

Q. And what qualifications must a person have * * *.

* * * * *

[231] Do you have Exhibit 3 in front of you?

A. Yes.

Q. I'd like to direct your attention to the last paragraph on that page.

A. On the first page?

Q. Yes, on the first page. Never mind. Generally, what are some of the considerations that a physician takes into account when determining what the best or most appropriate abortion procedure is in a particular circumstance to save the life or preserve the health of a woman?

A. Within the context of the statement?

Q. No, in general. What types of considerations does a doctor look at when determining what abortion procedure would be best for a patient—determine with the patient what would be best for her either to preserve her health or save her life?

A. The similar things to those we would have discussed within the committee, which are the patient's general state of health, the nature of the disease process, the options available and their [232] particular risks in light of that individual patient's medical circumstances, and the patient's autonomous choice among the options presented.

Q. Okay. And what are some aspects of the D&X procedure that might lead a physician to conclude that a D&X is the best or most appropriate abortion procedure to save the life or preserve the health of a woman?

A. One of the elements that came up among the different and numerous examples was the decreased instrumentation and the ability to preserve a relatively intact fetus for evaluation, particularly for some genetic based congenital anomalies.

Q. And why would less instrumentation be beneficial?

A. It depends on the circumstance. In the circumstance of septic abortions, any increase in instrumentation might increase the ability of bacteria to enter the blood stream. In the case of tropoblastic disease, increased instrumentation is likely to transport tropoblastic disease, which is a form of cancer, to [233] other areas such as the lung.

Q. And I believe you testified earlier—correct me if I'm misstating your testimony—that at the annual clinical meeting each year, members have an opportunity if they want to discuss policy statements; is that correct?

A. To discuss areas around policy statements, yes.

Q. Was there an annual clinical meeting held after the approval of the 1997 statement, Exhibit 3?

A. There is an annual clinical meeting held on an annual basis.

Q. It wasn't skipped after the statement was written; correct?

A. No.

Q. And the same holds true for after the 2000 statement was written? Was there an annual clinical meeting after that one?

A. That would be correct.

Q. And earlier, you testified that the fact sheet, Exhibit 5, I believe, was sent to you, and you submitted edits back to ACOG; is that correct?

[234]

A. That's correct.

Q. And were those edits incorporated into the fact sheet?

A. You know, I didn't go back and look.

Q. If I represent to you that Congress claims that an ethical consensus exists that the practice of partial-birth abortion "is a gruesome and inhumane procedure that should be prohibited," as a member of the ACOG task force on partial-birth abortion, do you believe there's such an ethical consensus?

A. No.

Q. If I represent to you that Congress claims that partial-birth abortion confuses the ethical duties of physicians to preserve and promote life, as a member of the ACOG task force on partial-birth abortion, do you agree that the ethical duties of physicians are confused in that way?

A. No.

Q. Exhibit 4, I'd like you to look at Exhibit 4, please. As far as you know, are all the statements in Exhibit 4 currently the position of [235] ACOG today?

A. It is my understanding.

Q. What is ACOG's current position regarding how, if at all, the federal Partial-Birth Abortion Ban Act of 2003 would affect the physician/patient relationship?

A. I believe that the statement of policy continues the same with the statement that the intervention of legislative bodies into medical decisionmaking is inappropriate, ill-advised, and dangerous, and that is in regards to interfering in the physician/patient relationship.

Q. What is ACOG's current position regarding how, if at all, the federal Partial-Birth Abortion Ban Act of 2003 would affect a physician's medical and ethical duties toward his or her patients?

A. I think that's out of the scope.

Q. What is ACOG's current position regarding the effect, if any, that the federal Partial-Birth Abortion Ban Act of 2003 would have on women's health?

MR. EDELMAN: That's also outside the * * *.

* * * * *